Mark M. Bettilyon (4798)
Rick B. Hoggard (5088)
Arthur B. Berger (6490)
Samuel C. Straight (7638)
RAY QUINNEY & NEBEKER P.C.
36 South State Street, Suite 1400
Salt Lake City, Utah 84111
Telephone: (801) 532-1500
Facsimile: (801) 532-7543
mbettilyon@rqn.com
rhoggard@rqn.com
aberger@rqn.com
sstraight@rqn.com

David B. Thomas – (3228)
Office of the General Counsel
Brigham Young University
A-350 ASB
Provo, Utah 84602
Telephone: 801-422-4722
Facsimile: 801-422-0265
Dave_Thomas@byu.edu

Leo R. Beus (admitted *pro hac vice*)
L. Richard Williams (admitted *pro hac vice*)
Mark C. Dangerfield (admitted *pro hac vice*)
Adam C. Anderson (admitted *pro hac vice*)
Keith C. Ricker (admitted *pro hac vice*)
BEUS GILBERT PLLC
4800 North Scottsdale Road, Suite 6000
Scottsdale, Arizona 85251
Telephone: 480-429-3000
Facsimile: 480-429-3100
lbeus@beusgilbert.com
rwilliams@beusgilbert.com
mdangerfield@beusgilbert.com
aanderson@beusgilbert.com
kricker@beusgilbert.com

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH CENTRAL DIVISION

BRIGHAM YOUNG UNIVERSITY, a Utah Non-Profit Education Institution; and Dr. DANIEL L. SIMMONS, an individual, Plaintiffs, vs. PFIZER, INC., a Delaware Corporation, G.D. SEARLE & COMPANY, a Delaware corporation, G.D. SEARLE LLC, a Delaware Limited Liability Company, MONSANTO COMPANY, a Delaware Corporation; and PHARMACIA CORPORATION, a Delaware Corporation, Defendants.	Case Number: 2:06CV-890-BTS (BCW) **FIRST AMENDED COMPLAINT (REDACTED VERSION)** **JURY TRIAL DEMANDED** (Breach of Contract; Breach of Fiduciary Duty; Correction of Inventorship; Unjust Enrichment; Fraud; Negligent Misrepresentation; Misappropriation of Trade Secrets; Violation of 18 U.S.C. § 1961, *et seq*) Judge Ted Stewart Magistrate Judge Brooke C. Wells

TABLE OF CONTENTS

Page

I. INTRODUCTION

1. Brigham Young University and Dr. Daniel L. Simmons (where appropriate, "Brigham Young University") bring this First Amended Complaint based on new facts they have learned since filing their original complaint on October 18, 2006.

2. Dr. Daniel L. Simmons, a professor at Brigham Young University, discovered COX-2, one of the most important pharmacological discoveries of the last two decades.

3. In early 1991, Dr. Simmons took his discovery of COX-2 and his project to find a COX-2 selective NSAID to Monsanto. Brigham Young University and Monsanto then entered into a "Research Agreement" (attached as Exhibit A). The Research Agreement described a "Project" on which the parties would collaborate, in an attempt, among other things, to isolate a new anti-inflammatory drug that would act by selectively inhibiting the activity of COX-2. The Research Agreement required that Monsanto notify Brigham Young University of patentable results arising from the Project and provided that Brigham Young University would be entitled to a reasonable royalty from such patentable results.

4. Pursuant to the parties' collaboration, and as provided for by the Research Agreement, Brigham Young University and Dr. Simmons provided Monsanto Dr. Simmons's discovery and valuable Confidential Information for use in the Project.

5. In breach of the Research Agreement and acting in bad faith, Monsanto, through Dr. Philip Needleman, Monsanto's Chief Scientific Officer, fraudulently terminated the Research Agreement and secretly misappropriated Dr. Simmons's discovery and the Project for its own gain.

6. As Brigham Young University has learned since filing its original complaint, Monsanto's misappropriation of the Project was part of a broader fraudulent scheme to enable Monsanto and its successors to usurp, protect and enhance profits from COX-2 related drugs. To

carry out that scheme, Monsanto, its pharmaceutical subsidiary, Searle, and their successors, Pharmacia and Pfizer, organized an association of entities (the "COX-2 Project Enterprise") to conduct a pattern of activity in violation of 18 U.S.C. § 1962(c).

7. With the benefit of Dr. Simmons's discovery and Brigham Young University's Project, Monsanto was the first pharmaceutical company with the capability of systematically testing and identifying a COX-2 selective inhibitor. With that advantage, Monsanto was the first to market this type of drug. By Monsanto's own admission, the discovery of COX-2 was "critical" to the creation of what Monsanto called its "super aspirin," the COX-2 selective nonsteroidal anti-inflammatory drug ("NSAID"), Celebrex.

8. According to Dr. Needleman, "[i]n drug development, time really is money." For an "average" pharmaceutical (with peak sales of $356 million per year), Dr. Needleman has written, "for each day the drug development is accelerated, there is $1 million added to the Company's sales figures." But for Celebrex, Dr. Needleman wrote, "this figure could approach $10 million per day."

9. Not only did it misappropriate the Project, Monsanto, with the help of Pfizer and other members of the COX-2 Project Enterprise, developed and implemented a marketing campaign intended to convince the scientific community, medical practitioners, and the public that Monsanto and Searle, though Dr. Needleman's laboratory, not Dr. Simmons, discovered COX-2. Monsanto did so because it had concluded that portraying itself with REDACTED in the development of the drug would give it a sales advantage.

10. As part of the same scheme to enhance its COX-2 related profits, Monsanto and its successors, again with the help of other members of the COX-2 Project Enterprise, fraudulently marketed its second-generation COX-2 selective inhibitor, Bextra, for uses not

approved by the FDA, thereby continuing its pattern of activity in violation of 18 U.S.C. § 1962(c).

11. Indeed, since Monsanto first fraudulently took the COX-2 Project from Brigham Young University and Dr. Simmons, Monsanto and its successors have used fraudulent marketing and fraudulent concealment of the truth as a regular way of doing business to carry out the objectives of its COX-2 Project Enterprise. In doing so, Monsanto and its successors have kept all the profits from the sales of Celebrex, Bextra, and other COX-2 selective inhibitors. Those profits have been enormous—Celebrex and its second-generation drugs are some of the most commercially successful medications of the last century, with total sales to date well over $42 billion.

12. Monsanto and its successors fraudulently concealed all these facts until recent Monsanto litigation caused them to admit that, before meeting Dr. Simmons, Monsanto did not have COX-2 or a COX-2 selective NSAID project and, in fact, was heading down another research path that would never have led to Celebrex.

13. During this litigation, and as part of the COX-2 Project Enterprise, Pfizer (which acquired Monsanto in 2003) has hidden highly relevant documents from Brigham Young University, in some cases by misrepresenting that the documents did not even exist. For example, Pfizer, through Sidley Austin, its outside lawyers, misrepresented that documents confirming Monsanto's use of Brigham Young University's materials and confidential information did not exist because those materials "did not work" and had not been used. Pfizer then withheld critical documents showing that Brigham Young University's materials not only worked, but that Monsanto had successfully used them to gain a critical advantage in the development of Celebrex and other COX-2 inhibitors.

14. Brigham Young University and Dr. Simmons reassert their demand for a jury trial and seek damages caused by the Defendants' misconduct.

II. PARTIES

15. Plaintiff Brigham Young University is a private not-for-profit university located in Provo, Utah. Brigham Young University did not use any money from either the state or federal government to fund the research at issue in this First Amended Complaint.

16. Plaintiff Dr. Daniel L. Simmons is a professor of biochemistry and chemistry at Brigham Young University. Dr. Simmons holds a Ph.D. from the University of Wisconsin – Madison. Prior to joining the faculty at Brigham Young University in 1989, he was a Harvard University postdoctoral fellow.

17. Defendant G.D. Searle LLC ("Searle LLC") is a Delaware Limited Liability Company with its principal place of business in Illinois. Searle does business and sells products throughout the United States, including in Utah. Searle LLC is the successor to Defendant G. D. Searle & Company ("Searle Co."). Searle Co. and Searle LLC shall be referred to jointly in this First Amended Complaint as "Searle."

18. Defendant Monsanto Co. ("Monsanto") is a Delaware corporation with its principal place of business in St. Louis, Missouri. Monsanto does business and sells products throughout the United States, including in Utah. Monsanto is registered with the Utah Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah.

19. Defendant Pharmacia Corp. ("Pharmacia") is a Delaware corporation with its principal place of business in New Jersey. Pharmacia does business and sells products throughout the United States, including in Utah. Pharmacia is registered with the Utah

Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah.

20. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York. Pfizer does business and sells products throughout the United States, including in Utah. Pfizer is registered with the Utah Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah.

21. The Defendants are related as follows: (1) in 1985, Monsanto acquired Searle Co., making Searle Co. its pharmaceutical unit; (2) in or around 1998, Pfizer and Monsanto entered into a joint venture to market Celebrex; (3) in April 2000, Monsanto and its Searle Co. unit merged with Pharmacia & Upjohn, Inc. to form Pharmacia; (4) in 2000, Searle Co. changed its corporate form becoming Searle LLC; (5) in 2002, Pharmacia spun off Monsanto's agricultural operations; and finally (6) in April 2003, Pfizer and Pharmacia merged leaving Pfizer in control of Pharmacia and Searle.

22. On information and belief, Pfizer has assumed Monsanto, Searle, and Pharmacia's liabilities which arise from the wrongful activities of the Defendants, described in the body of this First Amended Complaint. Moreover, Pfizer continued the fraudulent concealment of the other Defendants' wrongful acts. As more fully described in this First Amended Complaint, Pfizer, during the joint venture to market Celebrex and after acquiring Pharmacia/Monsanto, also committed additional wrongful acts of its own.

23. Alternatively, Monsanto, Searle, and Pharmacia retain some portion of this liability.

24. All Monsanto and/or Searle employees described herein, including but not limited to, Dr. Needleman, Dr. Masferrer, Dr. Seibert, and Dr. Haymore, were at all relevant times acting

in the course and scope of their employment. During the early months of the collaboration, Drs. Seibert and Masferrer were post-doctoral fellows at Washington University and worked in a laboratory run by Monsanto's Dr. Needleman, who at the time had responsibilities at both Monsanto and Washington University. During that same time period, Drs. Seibert and Masferrer entered into consulting agreements with Monsanto and accepted permanent employment with the company. In all contacts with Brigham Young University and Dr. Simmons, Drs. Seibert and Masferrer were acting as Monsanto and/or Searle's agent, as part of the COX-2 Project Enterprise. Therefore, liability arising from their dealings with Brigham Young University and Dr. Simmons is attributable to Monsanto and/or Searle and their successors and assigns, including Pharmacia and Pfizer.

III. JURISDICTION AND VENUE

25. This Court retains jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a). As stated above, each of the Defendants is a Delaware Corporation or limited liability company with its principal place of business outside the State of Utah; Plaintiffs Brigham Young University and Dr. Simmons are both residents of the State of Utah.

26. The amount in controversy in this action exceeds $75,000, exclusive of interest and costs.

27. Furthermore, this Court retains original subject matter jurisdiction, pursuant to 28 U.S.C. § 1331 over Plaintiffs' Claims arising under 35 U.S.C. § 256.

28. Furthermore, this Court has original subject matter jurisdiction over Plaintiffs' Claims pursuant to 18 U.S.C. 1961, *et seq*.

29. Venue is proper in this Court under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims herein occurred within the State of Utah.

30. Furthermore, pursuant to 28 U.S.C. § 1391(c), each of the Defendant corporations is subject to personal jurisdiction in Utah and is, therefore, deemed to reside within this district as stated above in Section II. Each of the Defendant corporations has substantial, continuous, and systematic contacts with the State of Utah.

31. Additionally, the events giving rise to this litigation arise from the Defendants' contacts with the State of Utah.

32. Many of the witnesses who will testify concerning the events giving rise to this litigation are residents of the State of Utah.

33. Finally, venue is proper in this Court pursuant to 18 U.S.C. § 1965.

IV. FACTS

A. The History Of Pain Medication: NSAIDs And Steroids

1. NSAIDS

34. Aspirin has been used since 1899 for the treatment of inflammation, pain, and fever. Since then, pharmaceutical companies have developed many other drugs which are similar to aspirin. These medications are called non-steroidal anti-inflammatory drugs or NSAIDS.

35. The key to how aspirin and other NSAIDs work is an enzyme commonly called cyclooxygenase or COX. COX produces molecules called prostaglandins, that are responsible for inflammation, pain, and fever. However, prostaglandins also have beneficial effects such as promoting protective mucus secretion in the stomach.

36. NSAIDs work by binding to COX and blocking it from making prostaglandins.

37. While NSAIDs inhibit inflammation, pain, and fever, their frequent use can cause many troubling and dangerous side effects such as gastric distress, ulcers, kidney damage, and even a rare type of asthma. Problematically, NSAIDs indiscriminately prevent the production of all prostaglandins, thus eliminating both the negative effects (pain, inflammation, and fever) and

the beneficial effects (protection of the stomach) resulting in NSAID-induced ulcers that reportedly kill over 16,000 Americans a year.

38. In the 1960s and 1970s, many potent NSAIDs were discovered, including ibuprofen (Motrin or Advil), naproxen (Aleve), sulindac (Clinoril), diclofenac (Voltaren), ketoprofen (Orudis), piroxicam (Feldene), indomethacin (Indocin), and meclofenamate (Meclomen).

39. By the early 1990s, the NSAID market was saturated. Drug companies had little interest in developing yet another NSAID that had the same level of efficacy and carried the same troubling side effects as existing drugs.

2. Steroids

40. Steroids provide an alternative to NSAIDs for treatment of pain and inflammation. Unlike NSAIDs, steroids do not bind to COX to inhibit the production of prostaglandins. Instead, steroids act earlier by preventing the COX gene from producing the COX enzyme. Since 1950, drug companies have made many synthetic anti-inflammatory steroids, including prednisolone, prednisone, betamethasone, and dexamethasone.

41. Anti-inflammatory steroids (sometimes referred to as glucocorticoids) have their own dangerous side effects and can cause a number of ailments, including nausea, bone pain, potassium loss, muscle weakness, thinning skin, glaucoma, depression, hypertension, metabolic disturbances, growth retardation, immune suppression, and adrenal gland shutdown.

42. By the mid 1980s, drug researchers were looking for a way to inhibit pain, inflammation, and fever that did not have the negative side effects associated with either existing NSAIDs or steroids.

B. Drug Researchers Identified One COX With Different Behaviors

43. Until Dr. Simmons's identification of a second COX gene and enzyme, researchers did not understand why COX appeared to act differently under various physiological conditions. For example, researchers observed that COX usually produced a constant level of prostaglandins but, at times, in response to a stimulus like injury or infection, the production of prostaglandins spiked. Researchers developed various theories to try to explain why COX behaved in this way.

44. For example, some laboratories, including Dr. Needleman's, theorized the possible existence of multiple COX "pools," the existence of multiple messenger ribonucleic acids ("mRNAs") generated from the same COX gene, or even the existence of multiple COX genes.

45. In formulating these theories, researchers, including Dr. Needleman, were hindered because they had not identified or isolated two separate COX genes that produce two separate and distinct COX enzymes. Nor had researchers identified the separate and distinct amino acid sequences for the two enzymes—understanding the distinctions between those sequences were critical to the later effort to find an NSAID that could selectively inhibit COX-2.

C. Monsanto's Steroid-like Research Was Premised On A Single COX Target

46. In 1989, Monsanto hired Dr. Needleman from Washington University in St. Louis as its Chief Scientific Officer. Brigham Young University has recently learned from a review of other Monsanto litigation that about the time of Dr. Needleman's arrival, Monsanto began a research project seeking to find a new and novel steroid-like solution to inflammation and pain.

47. Monsanto and Dr. Needleman were not interested in developing an NSAID-like compound because they thought it would be like the many other NSAIDs already on the market and would have the same side effects. Thus, before Monsanto's collaboration with Dr. Simmons,

Monsanto was testing chemicals to develop a steroid-like drug and was eliminating any compound found to have NSAID activity.

48. In other words, Monsanto's steroid-like project assumed that there was no way to make a better or different NSAID (a "super aspirin") because, at the time, Monsanto could not distinguish "constitutive" versus "inducible" COX activities as being distinct targets for potentially selective NSAIDs. As described in further detail below, Dr. Peter Isakson, the eventual head of Monsanto's COX-2 Project, submitted a sworn statement on August 23, 1999 in separate litigation stating that at the time this steroid-like project was being carried out, Monsanto was [redacted]

REDACTED

D. Dr. Simmons Discovered COX-2

49. By the end of 1988, while working as a Harvard fellow, Dr. Simmons had isolated various mRNAs which were induced (or turned on) to relatively high levels by cancer-causing agents. Dr. Simmons, searching for a cancer cure, isolated these mRNAs (called "immediate early" mRNAs) to study their role in the aberrant division of cancer cells.

50. One of the mRNAs Dr. Simmons isolated was named, for laboratory purposes, CEF 147.

51. After coming to Brigham Young University in July 1989, Dr. Simmons, working with his graduate student, Weilin Xie, determined CEF 147's nucleic acid sequence and predicted amino acid sequence. He then quickly recognized that CEF 147 encoded a novel COX, distinguishable from the only COX previously identified. Dr. Simmons named this new COX "mitogen-inducible prostaglandin G/H synthase," a scientifically precise name for the second form of COX. Over time, this became popularly known as "COX-2."

52. Dr. Simmons found that CEF 147 encoded a COX that shared about 60% of the protein sequence identity with the then-known COX and shared all the identifying characteristics of a cyclooxygenase. Because CEF 147 shared (with COX) molecular characteristics known to be essential for COX to make prostaglandins but differed from COX in other respects, it was apparent to Dr. Simmons that this was a new and different COX and a potential drug target. Dr. Simmons later conveyed this critical information to Monsanto as part of the Project.

53. As a result of Dr. Simmons's discovery, scientists now understand that one COX enzyme (now called COX-1) produces the "constitutive" or constant level of prostaglandins, and a second COX enzyme (now called COX-2) produces the "inducible" level of prostaglandins resulting from a stimulus.

54. Dr. Simmons immediately understood the significance of his discovery. In October 1989, he submitted a notarized document to the Chairman of the Department of Chemistry at Brigham Young University outlining his discovery. After describing his research, Dr. Simmons observed that his discovery was likely a very important contribution to pharmacology. He explained that, because there are two different COX enzymes, it would be possible to test for NSAIDs that bind and inhibit one or the other and thus reduce pain, fever, and inflammation without the unwanted side effects. In other words, Dr. Simmons had found a new target (COX-2) to use in developing a potential pain and inflammation blocker. Dr. Simmons also noted in his document that the identification of COX-2 might lead to COX-2 selective NSAIDs with cancer cell antigrowth properties, resulting in new forms of chemotherapy. Both of Dr. Simmons's early predictions proved correct.

55. In 1990, Dr. Simmons performed additional studies on COX-2. He synthesized COX-2 in a test tube and showed that it had many of the critical physical features of COX. He

generated an antibody to COX-2 to enable and aid its detection in tissues and cells and cloned mouse COX-1 and COX-2. By early 1991, he had conducted additional experiments measuring the levels of COX-1 and COX-2 expression in tissue and cells, confirming that the COX-1 gene was responsible for the "constitutive" activity of COX and that the COX-2 gene was responsible for the "inducible" activity of COX.

56. In April 1991, Dr. Simmons published his discovery of COX-2 and related findings in the Proceedings of the National Academy of Sciences. However, he did not disclose the nucleic acid sequence of mouse COX-2, reserving this and other proprietary information for an anticipated collaboration with an industrial partner.

E. Dr. Simmons Seeks A Collaboration To Develop A COX-2 Selective NSAID

57. In February of 1991, Dr. Barry Haymore, a Monsanto scientist working for Dr. Needleman, came to Brigham Young University to present a seminar on a subject unrelated to COX. According to Dr. Haymore, one of his responsibilities was to scout for new scientific developments that might be of benefit to Monsanto. Dr. Simmons met with Dr. Haymore and told him he had identified COX-2. Dr. Simmons explained the importance of his discovery in the treatment of pain and inflammation, focusing on the possibility of creating a testing system to find an NSAID capable of selectively inhibiting COX-2. Dr. Simmons revealed to Dr. Haymore that he not only had identified COX-2, but had actually cloned COX-2 in both chicken and mouse. Dr. Simmons told Dr. Haymore that he was seeking an industrial collaborator to pursue a project to find, among other things, an NSAID that would selectively inhibit COX-2.

58. Dr. Haymore said he would take Dr. Simmons's discovery directly to Dr. Needleman. Just days later, Dr. Haymore called Dr. Simmons and told him that Monsanto was very interested in Dr. Simmons's COX-2 research and the potential for a business collaboration with Brigham Young University.

59. Dr. Haymore asked Dr. Simmons to come to Monsanto to present a seminar on COX-2. Dr. Haymore also requested that Dr. Simmons send Monsanto certain documentation. Based on Monsanto's representation that it was interested in a business relationship with Brigham Young University, Dr. Simmons sent the requested materials and agreed to give the seminar at Monsanto.

60. On April 5, 1991, Dr. Simmons made a presentation at Monsanto, describing his discovery of COX-2 and his cloning of COX-2 in chicken and in mouse. He also met with Dr. Needleman and presented Monsanto with a written proposal for collaboration between Brigham Young University and Monsanto.

61. During this same visit, Dr. Simmons went out to dinner with Monsanto personnel. Dr. Simmons asked them about his patent rights on his COX-2 technology which included his isolated COX-2 and COX-2 cDNA clones, their predicted amino acid sequences and nucleic acid sequences, and his COX-2 antibodies. Dr. Simmons also asked if a method of testing NSAIDs created through his discovery of COX-2 were patentable. They wrongly advised Dr. Simmons that he should not patent these items because any such patent would not be enforceable or defensible.

62. The focus of Dr. Simmons's April 5, 1991 written proposal to Monsanto was the creation of an NSAID that would selectively inhibit COX-2. Also, with Dr. Simmons's methodology, drugs could be found that would selectively inhibit COX-1. The proposal envisioned the creation of drugs that would regulate each COX enzyme separately.

63. In addition to some modest initial funding, Dr. Simmons's proposal sought a full collaboration with Monsanto scientists to pursue the interaction of NSAIDs with COX-2,

including the provision of NSAIDs for testing and the provision of advice and participation in the Project.

64. Dr. Needleman told Dr. Simmons that he was impressed with Dr. Simmons's April 5, 1991, presentation. Dr. Needleman indicated that Monsanto was interested in collaborating with Dr. Simmons and Brigham Young University.

65. On April 11, 1991, six days after Dr. Simmons's seminar and meetings at Monsanto's corporate headquarters, Monsanto sent a proposed research agreement to Brigham Young University.

66. Dr. Needleman personally handled the negotiations between Brigham Young University and Monsanto. Dr. Needleman represented that the research agreement he was offering Brigham Young University was the same agreement Monsanto gave him when he was a professor at Washington University. Dr. Needleman repeatedly assured Dr. Simmons that this agreement fully protected Dr. Simmons and gave Brigham Young University rights to and ownership of the results of the collaborative Project with the right of Monsanto to license any technology.

67. From April 21-25, 1991, during a conference in Atlanta, Monsanto scientists Drs. Seibert and Masferrer met with Dr. Simmons at Dr. Needleman's request. During this meeting they told Dr. Simmons that he "had no idea how big" the result of the collaboration between Monsanto and Dr. Simmons would become if Dr. Simmons "worked with" Monsanto. They represented that the collaboration would lead to tremendous new NSAIDs that would be very profitable to both Brigham Young University and Monsanto.

68. At this same conference, Drs. Seibert and Masferrer expressed excitement over the agreed-upon collaboration and the desire to begin collaborating immediately, requesting that Dr. Simmons begin sending his technology.

69. On April 29, 1991, Dr. Simmons provided Monsanto with his murine (mouse) COX-1 and COX-2 clones and COX-2 antibodies.

70. On May 23, 1991, Dr. Simmons provided Monsanto with a copy of his submitted National Institutes of Health ("NIH") grant proposal containing detailed information about the role of COX-2 in cancer and the potential of COX-2 as a target for anti-cancer therapy.

71. Both the draft agreement that Brigham Young University received prior to April 29, 1991, and the subsequently signed final Research Agreement made clear that the parties intended for Dr. Simmons's murine COX-1 and COX-2 clones, COX-2 antibodies, and the information in the NIH grant proposal be covered by the Research Agreement's Article 4 on Confidential Information.

72. Paragraph 4.1 of both the draft and final Research Agreement included as "CONFIDENTIAL INFORMATION": "proprietary information, including information relating to transformed cells, genes, transformation vectors, transformation, selection and regeneration procedures, media formulations, chemicals, DNA sequences and probes …."

73. In short, ¶ 4.1 described exactly the information Dr. Simmons gave Monsanto with the promise and understanding that the Research Agreement would cover that information and protect Brigham Young University and Dr. Simmons.

74. Dr. Simmons provided Monsanto with his murine COX-1 and COX-2 clones and COX-2 antibodies and the NIH grant proposal in reliance upon, among others, the following: (1) Monsanto's representation that Brigham Young University would have the same contractual

protections that Dr. Needleman had at Washington University, (2) Monsanto and Brigham Young had agreed to a full collaboration, and (3) the understanding that the transmitted technology and information would be covered by the terms of the written confidentiality provisions as reflected in the draft agreement.

75. Monsanto required Dr. Simmons's consent before they could use his trade secrets, including his technology and NIH grant proposal. That consent was granted by the Agreement and included the trade secrets given before signing. If the Confidential Information/trade secrets exchanged prior to signing were not covered by the Research Agreement, Monsanto had not otherwise received consent to use them.

76. On September 30, 2009, Judge Kimball confirmed that the biological materials and related information that Dr. Simmons and Brigham Young University provided to Monsanto were protected Confidential Information governed by Research Agreement Article 4. As Judge Kimball put it, "there is abundant evidence that both parties intended that materials submitted by BYU … were to be maintained as confidential."

F. Brigham Young University And Monsanto Sign The Collaborative Research Agreement

77. By July 8, 1991, Monsanto and Brigham Young University signed the Research Agreement. Dr. Needleman signed for Monsanto; Associate Academic Vice President J. Bevan Ott signed for Brigham Young University.

78. Paragraph 1.1 describes the "PROJECT" as the "research programs described in Appendix 'A'."

79. Appendix A describes one of the research programs encompassed by the Project in the following terms: "Our laboratory will use the antibodies and cDNA probes that we [Brigham Young University] have generated to COX-1 and COX-2 in chicken, mouse and

human to explore the nature of the nonsteroidal anti inflammatory drug (NSAID) interaction with these enzymes." The first listed Project goal is to find a specific COX-1 and COX-2 selective NSAID: "Identification of Isoenzyme-specific Inhibition of Cyclooxygenase (COX) Activity."

80. Appendix A also includes other topics within the scope of the Project including the testing of NSAIDs' interaction with COX in the treatment of cancer and the possible role of COX-2 in wound healing, bone resorption and ovulation.

81. In consideration for Brigham Young University agreeing to disclose Dr. Simmons's discovery and related research results, Monsanto agreed that the collaborative "PROJECT" would be "carried out under the direction of Dr. Daniel L. Simmons."

82. The Research Agreement required Brigham Young University to "furnish such available laboratory facilities and equipment as it shall determine necessary for the work to be done on this PROJECT."

83. On the other hand, the Research Agreement required that, "MONSANTO shall furnish prostaglandins, NSAIDs and consulting services to the extent provided in Appendix 'A' and, in addition shall pay [Brigham Young University] the sum of Fifty-Thousand Dollars ($50,000.00) per year." Appendix A provided that Brigham Young University and Dr. Simmons would "test as many NSAIDs as [they] can obtain."

84. Pursuant to the Research Agreement, Dr. Simmons would test NSAIDs sent to him by Monsanto in Brigham Young University's laboratory.

85. The Research Agreement anticipated that Brigham Young University and Monsanto would share confidential scientific information for the purpose of cooperating in the search for a COX-2 selective NSAID. For example:

(a) ¶ 1.2 states: "'MONSANTO INFORMATION' shall mean all technical and biological information and know-how that is received by UNIVERSITY directly or indirectly from MONSANTO…."

(b) ¶ 4.1 states: "In order for the parties to more fully cooperate in this effort, it may be necessary for UNIVERSITY or MONSANTO to disclose to the other party proprietary information, including information relating to transformed cells, genes, transformation vectors, transformation, selection and regeneration procedures, media formulations, chemicals, DNA sequences and probes which information (including MONSANTO INFORMATION) is confidential and proprietary and is hereafter referred to as CONFIDENTIAL INFORMATION."

86. Throughout Dr. Simmons's relationship with Monsanto, he was in frequent contact to update Monsanto with new developments from Brigham Young University's laboratory and also to answer Monsanto's questions in an effort to help them better understand COX-2.

87. Monsanto and Brigham Young University agreed that any shared Confidential Information could not be used for purposes other than the cooperative effort to find a COX-2 selective NSAID. For example:

(a) ¶ 4.1 states "The parties agree that CONFIDENTIAL INFORMATION will be used only as provided for in this Agreement…."

(b) ¶ 4.1(b) limits "disclosure of CONFIDENTIAL INFORMATION to those personnel who need such access for purposes of this cooperative effort…."

(c) ¶ 4.1(c) states the parties shall "not duplicate or use CONFIDENTIAL INFORMATION in any other manner …."

88. The Research Agreement described the Project as being the cooperative effort to develop a COX-2 selective NSAID (or to achieve the other stated objectives) with the use of Confidential Information.

89. Other provisions of the Research Agreement confirm that the Project would only be carried out pursuant to the anticipated cooperative effort. For example:

(a) ¶ 1.6 requires Monsanto to furnish prostaglandins, NSAIDs and consulting services to Brigham Young University. It was Brigham Young University's intent

and Monsanto's purported intent that Monsanto contribute its considerable technical knowledge to help achieve the PROJECT objectives and that Monsanto could not withhold the most promising NSAIDs for its own secret Project.

(b) ¶ 1.3 states "The PROJECT and all work assigned shall be carried out under the direction of Dr. Daniel L. Simmons…." It was Brigham Young University's intent and Monsanto's purported intent that Monsanto could not do PROJECT work outside the cooperative effort and hide the work from Dr. Simmons's direction or knowledge.

(c) ¶ 3.1 contemplates that Brigham Young University and Monsanto may be "joint inventors" of "discoveries and inventions." It was Brigham Young University's intent and Monsanto's purported intent that they work in a cooperative effort to develop a COX-2 selective NSAID.

(d) ¶ 3.3 states: "In the event that MONSANTO determines that research results obtained from the PROJECT are patentable, it shall notify UNIVERSITY and thereafter indicate to UNIVERSITY its interest in a license under such prospective patents." Monsanto could not seek patents on patentable research results without first notifying Brigham Young University. ¶ 3.5 gave Brigham Young University direct access to Monsanto's attorneys to file and prosecute resulting patent applications. It was Brigham Young University's intent and Monsanto's purported intent that Monsanto could not take Dr. Simmons's CONFIDENTIAL INFORMATION to set up a parallel Project, and unilaterally benefit from the patentable results. To do so would deprive Brigham Young University of the agreed-upon consideration.

(e) ¶ 3.4 states that the reasonable royalty would be determined based upon, among other factors, Brigham Young University and Monsanto's "financial and scientific contributions to the research program under which the invention was made." It was Brigham Young University's intent and Monsanto's purported intent that they work in a cooperative effort to develop a COX-2 selective NSAID.

(f) ¶ 3.5 provides that Brigham Young University "shall have the right to designate, at its sole option, either MONSANTO'S Patent Department or a patent attorney in private practice to prepare, file and prosecute patent applications." Monsanto was required to inform Brigham Young University of any patentable research results so that Brigham Young University could exercise its right to protect itself by choosing its own patent counsel or by choosing to use Monsanto's patent attorneys.

(g) ¶ 3.3 and ¶ 3.5 are further bolstered by ¶ 3.6, which states that, "Until such time as MONSANTO notifies UNIVERSITY in writing that it no longer has an interest in a license, or until the expiration of the time specified in paragraph 3.4, MONSANTO agrees to bear the cost for filing and prosecution of patent applications under paragraph 3.5 and the issuance and maintenance of patents

thereon." Monsanto was required to notify Brigham Young University of Monsanto's intentions regarding research results from the PROJECT.

90. The above provisions, and the Research Agreement read in its entirety, establish that although Brigham Young University and Monsanto were assigned certain obligations, they were pursuing a "cooperative effort" to develop a COX-2 selective NSAID and accomplish the other Project aims. Any results of that cooperative effort, regardless of the relative contribution of either Monsanto or Brigham Young University, had to flow through the Research Agreement. Any attempt by Monsanto to test for and develop COX-2 selective NSAIDs using Confidential Information outside the Project would breach both the Research Agreement and Monsanto's fiduciary duty and duty of good faith and fair dealing.

91. Under ¶ 3.3 of the Research Agreement, if Monsanto determined that research results obtained from the Project were patentable, it was required to notify Brigham Young University. If Monsanto were interested in a license under such patents, Brigham Young University agreed to give Monsanto the right of first refusal for an exclusive license in exchange for payment to Brigham Young University of a reasonable royalty.

92. Dr. Simmons was excited to begin work with Monsanto and, based upon Monsanto's representation and the terms of the Research Agreement, viewed the Project with Monsanto as a full collaboration.

G. Monsanto Assumed A Fiduciary Duty

93. Monsanto assumed a fiduciary duty towards Brigham Young University and Dr. Simmons based on, among others, the following factors:

(a) ¶ 1.6 of the Research Agreement imposes upon Monsanto a duty to serve as Brigham Young University's consultant.

(b) The Research Agreement created a joint venture partnership between Brigham Young University and Monsanto by virtue of the parties' explicit mutual intent to each make contributions to the venture; share profits, risks of failure, and losses

resulting from the failure to produce results that are marketable; and exert mutual control over the operation of the PROJECT.

(c) Monsanto knowingly received Brigham Young University and Dr. Simmons's CONFIDENTIAL INFORMATION under the Research Agreement and thereby undertook to maintain this CONFIDENTIAL INFORMATION with exceptional care and skill.

(d) Monsanto assumed a position of trust and confidence over Brigham Young University and Dr. Simmons resulting from Monsanto's expertise and superior knowledge regarding pharmaceutical development, patenting, and marketing.

(e) Monsanto assumed a position of trust and confidence over Brigham Young University because it willingly accepted the contractual obligation that required Monsanto to protect certain of Brigham Young University's financial interests to the potential detriment of Monsanto's own financial interests. For example, Monsanto's duty under ¶ 3.3 of the Agreement to inform Brigham Young University of patentable research results from the Project would limit Monsanto's ability to conduct certain activities without first obtaining a license from Brigham Young University.

(f) ¶ 3.5 of the Research Agreement gives Brigham Young University the right to choose Monsanto's "patent attorneys to file and prosecute" patent applications on inventions arising from the Project. Because Brigham Young University was in a prospective attorney/client relationship with Monsanto's patent attorneys, Monsanto owed Brigham Young University a fiduciary duty to treat all Confidential Information received in a manner that would be in Brigham Young University's best interest.

94. As a result of this fiduciary relationship, Monsanto owed Brigham Young University a duty of loyalty and candor and was required to act in Brigham Young University's best interests.

95. However, as demonstrated below, Monsanto preyed upon Dr. Simmons and Brigham Young University's trust and confidence and breached its contractual and fiduciary duties to Brigham Young University. Evidence that has subsequently come to light demonstrates that no later than early 1992, Monsanto intended to misappropriate the Project and secretly develop its own COX-2 selective NSAID, thus depriving Brigham Young University and Dr. Simmons of the expected professional and economic benefits to which they were entitled. As

part of this fraudulent scheme, Monsanto (and later Pfizer) misrepresented Monsanto's role in COX-2 related discoveries and the state of Monsanto's COX-2 related knowledge prior to collaborating with Brigham Young University and Dr. Simmons.

H. Monsanto And Dr. Needleman Breach The Agreement

1. Monsanto and Dr. Needleman misappropriate Dr. Simmons's research

96. After collaborating with Brigham Young University and Dr. Simmons, Monsanto quickly understood the importance of Dr. Simmons's COX-2 discovery. As a result, Monsanto began to reduce its emphasis on steroid related research and shifted its focus to a search for a COX-2 selective NSAID.

97. By the spring of 1992, Dr. Needleman and Monsanto changed to a COX-2 Project looking for an NSAID solution to what they had just learned were two different and distinguishable COX enzymes. Monsanto did not inform Brigham Young University of this change. This was an abrupt corporate shift in thinking and approach requiring reallocation of valuable resources and personnel. It took place to further Monsanto's plan to convert the Project for its own gain.

98. It was not long before Monsanto found a promising COX-2 selective NSAID. Between January 8 and 11, 1992, Dr. Simmons and Dr. Seibert attended a seminar in Keystone, Colorado, where Dr. William Galbraith, a scientist working for a joint venture company, made a seminar presentation on a little-known, patented compound – DuP-697.

99. Dr. Galbraith explained that DuP-697 acted to reduce pain and inflammation but did not cause ulcers in test animals. Dr. Galbraith and his company thought that this compound might have some merit but did not understand why it worked because they did not have the

scientific knowledge or tools possessed by Dr. Simmons to distinguish COX-1 and COX-2 activity. DuP-697 had not been marketed because it possessed certain unwanted properties.

100. As a result of Dr. Simmons's discoveries, both Dr. Simmons and Dr. Seibert understood that DuP-697 could potentially be a COX-2 selective NSAID. However, Dr. Simmons believed that, because DuP-697 was under patent, the drug could not be used in the Project.

101. At the Keystone conference, Dr. Galbraith invited Dr. Simmons to speak on COX-2 at Dr. Galbraith's company and Dr. Simmons agreed. On that occasion, Dr. Galbraith asked Dr. Simmons to collaborate on testing DuP-697. Dr. Simmons declined, explaining that he had already agreed to collaborate with Monsanto.

102. Ironically and unbeknownst to Dr. Simmons, by early 1992, Monsanto had already secretly tested DuP-697 and other compounds against the COX-1 and COX-2 testing system that Monsanto developed using Confidential Information obtained from Dr. Simmons. The test results confirmed that DuP-697 and other compounds were potential COX-2 selective NSAIDs.

103. Monsanto also knew (but Dr. Simmons did not know) that it could potentially engineer around the DuP-697 patent. Furthermore, Monsanto believed it could isolate the DuP-697 properties that potentially inhibited COX-2 from its unwanted properties, thereby developing a lead compound for a COX-2 selective drug. By the end of June 1992, Monsanto had made numerous derivatives outside of the original DuP-697 patent.

104. Paragraph 1.6 and related provisions of the Research Agreement required Monsanto to send DuP-697 and derived compounds to Dr. Simmons for testing. Monsanto breached the Agreement, its fiduciary duty to Brigham Young University, and its duty of good

faith and fair dealing by not providing these NSAIDs to Brigham Young University and, instead, using them in its secret research.

105. Because Monsanto's testing of DuP-697, its derivative compounds, and other compounds was part of the Project, ¶ 1.3 required that it be carried out with Dr. Simmons's knowledge and direction.

106. Monsanto's secret research, including but not limited to compound testing, also violated the confidentiality provisions of Article 4 which limits the disclosure (and therefore use) of Confidential Information to those "personnel who need such access for purposes of this cooperative effort," meaning the Project. (See ¶ 4.1(b).)

107. Pursuant to ¶¶ 1.6 and 3.3 of the Research Agreement, its fiduciary duty, and its prior misrepresentations, Monsanto had a duty to advise Brigham Young University and Dr. Simmons of at least the following patentable results arising from the Project:

(a) The COX-2 gene as described by its nucleic acid sequence;

(b) The COX-2 enzyme as described by its amino acid sequence;

(c) Antibodies that bind to the COX-2 enzyme, but do not bind to the COX-1 enzyme;

(d) A cell line expressing the COX-2 enzyme;

(e) The method for using the COX-2 gene, enzyme, or cell line for the purpose of constructing a testing system to identify potential COX-2 selective NSAIDs; and

(f) A method of treating pain, inflammation, and fever by selectively inhibiting COX-2 activity in a human host. With Dr. Simmons's ability to test for COX-1 and COX-2 selectivity together with DuP-697 (which Monsanto secretly withheld), Brigham Young University and Dr. Simmons had all the components necessary to obtain a method of treatment patent.

108. These patents would have given Brigham Young University and Dr. Simmons the right to prevent others, without first obtaining a license from Brigham Young University, from

testing compounds for COX-2 selectivity, from conducting COX-2 related research, and from developing COX-2 selective NSAIDs for the purpose of commercial exploitation.

109. Monsanto was also required to provide notice of patentability to Brigham Young University, as described above, to correct its previous fraudulent misrepresentation that Dr. Simmons's COX-2 technology should not be patented.

110. Because Dr. Simmons was the first to isolate and purify COX-2 and its underlying gene sequence, his invention would have patent priority over those researchers who later discovered these same patentable phenomena.

111. Had Monsanto given Brigham Young University and Dr. Simmons notice that Dr. Simmons's COX-2 technology was patentable, they would have immediately understood the importance of identifying the human COX-2 enzyme and deriving its nucleic acid and amino acid sequences. Thus, Brigham Young University and Dr. Simmons would have been the first to obtain and own this very valuable and patentable invention.

112. Brigham Young University and Dr. Simmons did not begin to learn that certain of Dr. Simmons's COX-2 related discoveries and technology were patentable until, at the earliest, 1999, when he became aware that the University of Rochester had obtained a patent relating to COX-2 technology.

113. Pursuant to ¶ 1.6 and ¶ 3.3 and its fiduciary obligations, Monsanto also had a duty to notify Brigham Young University that Celebrex and its related compounds were "patentable results obtained from the PROJECT."

114. It was vital to Brigham Young University that Monsanto provide these notices of patentability because this was Brigham Young University's first significant biotechnology discovery and Monsanto knew that neither Brigham Young University nor Dr. Simmons

understood that Dr. Simmons's COX-2 technology was patentable. Brigham Young University held no biotechnology patents and had no patent attorneys on staff. Brigham Young University was contractually protected from its lack of familiarity in protecting biotechnology inventions because ¶ 3.3 required Monsanto to notify Brigham Young University of patentability and because ¶ 3.5 gave Brigham Young University access directly to Monsanto's patent attorneys to patent any inventions arising from the Project.

115. Instead of complying with these duties, including Monsanto's duty to notify Brigham Young University of patentable results from the Project, Monsanto breached the Research Agreement and its fiduciary duties and sought to further its own interests, perpetuate its previous fraudulent misrepresentations, and exclude Brigham Young University and Dr. Simmons from the professional and economic benefits to which they were entitled under the Project.

2. Dr. Needleman and Monsanto terminate the Research Agreement under fraudulent pretenses—committing predicate acts under 18 U.S.C. § 1962(c)

116. Throughout 1991 and the beginning of 1992, Dr. Simmons and Brigham Young University continued to collaborate with Monsanto. In July 1991, Dr. Simmons sent Dr. William Bradshaw, a colleague, to Monsanto to report on all activities at Brigham Young University and to deliver new developments and information.

117. Dr. Simmons's telephone logs show more than 60 calls to Monsanto during the period the Research Agreement was in effect. Additionally, he and his laboratory colleagues received many calls from Monsanto. During these calls, Brigham Young University and Dr. Simmons fully and candidly shared all relevant details of their technology, laboratory results, and accumulated knowledge of COX-1 and COX-2. Monsanto, however, never told Dr. Simmons and Brigham Young University of Monsanto's secret testing of DuP-697 and its

derivative compounds. Each of these telephone calls were made between the states of Utah and Missouri and were part of a scheme or artifice to defraud pursuant to 18 U.S.C. § 1343.

118. On March 17, 1992, after Monsanto had tested DuP-697 for COX-2 selectivity, Dr. Needleman, in a letter sent from Missouri to Utah by wire, abruptly announced his intent to terminate the Research Agreement with Brigham Young University—under pretense of not receiving sufficient communications from Dr. Simmons—writing "we should give serious consideration to ending the grant at the end of one year."

119. Dr. Simmons responded on March 20, 1992 with a detailed letter stating that he believed the communication channel was open and functioning as demonstrated by his conversations with members of Dr. Needleman's laboratory. Dr. Simmons also addressed specific questions posed by Dr. Needleman and expressed his desire to remain in an open collaboration with Dr. Needleman's laboratory.

120. Despite Dr. Simmons's response, in a March 23, 1992, letter sent from Missouri to Utah, which on information and belief was sent using the U.S. mail, Dr. Needleman stated five false and groundless reasons for ending the Research Agreement, including "1) that you only supplied us with the first bleed of your chicken based antibody and surely you did your own experiments with superior bleeds; 2) that you never included us in any aspect or discussion of the dexamethasone data while you knew that was a critical scientific interest of ours having discovered the phenomenon; 3) not informing us or sharing the RS-2 cells which could have been an extremely valuable screening tool for us; 4) the slowness with which you have proceeded in testing compounds; and 5) the ease with which you established outside collaborations but with no similar desire with our programs." Dr. Needleman concluded his letter by saying that he regarded the relationship as "an unworkable" collaboration.

121. Because of Monsanto's obvious determination to terminate the Research Agreement, Brigham Young University sent a letter to Monsanto on March 27, 1992, acknowledging the termination of the Research Agreement.

122. Brigham Young University sent this letter only because it was fraudulently induced to do so, being completely unaware that Monsanto's true reason for terminating the Research Agreement was to jettison Brigham Young University so Monsanto could secretly misappropriate the Project.

123. On May 20, 1992, Dr. Simmons wrote Dr. Needleman a letter refuting each of the five reasons Dr. Needleman had cited for termination. Dr. Simmons further expressed his dismay at the Project termination:

> [T]he statements that you made concerning the termination deserve a response, since they are largely in error and are likely due to inadequate or incorrect information communicated to you.

124. Dr. Simmons accompanied the letter with a "post-termination report" to Monsanto describing the results of the Project.

125. Monsanto did not respond to any of Brigham Young University or Dr. Simmons's letters.

126. By terminating the Research Agreement for fraudulent purposes, Monsanto breached its contractual and fiduciary duties to Brigham Young University and Dr. Simmons and wrongfully attempted to deprive Brigham Young University and Dr. Simmons of the intended benefits of the Agreement. Because Monsanto's termination was fraudulent, the Research Agreement remained in force and Monsanto was not relieved of its duties under the Research Agreement.

127. Other Research Agreement provisions explicitly extended beyond the term of the Agreement. For example, pursuant to Article 4, Confidential Information is protected for five

years from the "date of disclosure." As another example, Article 3 contemplates that reasonable royalty negotiations were to be completed within one year of the "issuance of a patent."

V. MONSANTO FRAUDULENTLY CONCEALED FROM BRIGHAM YOUNG UNIVERSITY AND DR. SIMMONS ITS BREACHES OF CONTRACTUAL AND FIDUCIARY DUTIES AND ITS THEFT OF BRIGHAM YOUNG UNIVERSITY'S TRADE SECRETS

128. From the fraudulent termination of the Research Agreement forward, Monsanto began a campaign to rewrite history by misrepresenting and concealing the true facts concerning its relationship with Brigham Young University. Monsanto concealed that it had secretly taken the Project and Confidential information to develop a COX-2 selective NSAID, including Celebrex, because it knew that it had breached the Research Agreement with Brigham Young University and that it had stolen Dr. Simmons and Brigham Young University's trade secrets. It also knew that Brigham Young University was entitled to a number of patents resulting from the Project. Monsanto and Dr. Needleman went to great efforts to distance themselves from Brigham Young University and Dr. Simmons and to avoid any reference to reliance on any information or technology received from Brigham Young University or Dr. Simmons. Monsanto and Dr. Needleman also went to great length to misrepresent their own COX-2 discoveries and the state of their COX-2 related knowledge prior to collaborating with Brigham Young University.

129. Monsanto's fiduciary relationship with Brigham Young University and Dr. Simmons obligated it to affirmatively "speak the truth." Its affirmative misstatements and deliberate omissions, as described in this First Amended Complaint, constitute fraudulent concealment. As a result, Brigham Young University and Dr. Simmons did not know, nor reasonably should have known, of their claim until they began to discover Monsanto's scheme.

A. Fraudulent Statements At The Prostaglandin Conference

130. From July 26-31, 1992, Dr. Simmons attended the "International Conference on Prostaglandins and Related Compounds" in Montreal. During the conference, Dr. Simmons invited Dr. Needleman to lunch. Dr. Needleman accepted. The lunch took place at a Chinese restaurant near the conference center.

131. Dr. Simmons's purpose for setting up the lunch was to persuade Dr. Needleman to reinstate the Research Agreement or, at a minimum, understand why Monsanto had acted so abruptly. This was Dr. Simmons's first opportunity to meet with Dr. Needleman since Monsanto had terminated the Research Agreement.

132. During the lunch, Dr. Simmons expressed his frustration that Monsanto had terminated the Research Agreement and refuted the reasons for termination.

133. Dr. Simmons described the progress Brigham Young University had made, explaining that his laboratory had identified a potential lead compound for a COX-2 selective NSAID. Of course, Dr. Simmons did not know, and Dr. Needleman did not disclose, that Monsanto was secretly using the Confidential Information to test and develop its own lead compounds derived from DuP-697.

134. Dr. Needleman denied that the reasons for terminating the Research Agreement were false and represented to Dr. Simmons that Monsanto had done nothing wrong in connection with its relationship with Dr. Simmons or Brigham Young University.

135. Dr. Simmons left the meeting frustrated that Monsanto had terminated the Research Agreement and feeling that Monsanto had treated him and Brigham Young University poorly. However, Dr. Simmons neither knew nor reasonably could have known that Monsanto had misappropriated the Project and related Confidential Information because of Dr. Needleman's misleading conduct.

136. At the end of the Montreal conference, Dr. Masferrer, a Monsanto scientist, approached Dr. Simmons in the foyer of the conference center and asked if he would provide him with RS2 cells, a special cell line used in Dr. Simmons's laboratory.

137. Dr. Simmons responded that, although he had no personal dispute with Dr. Masferrer and was willing to provide the cells to him personally, he was unwilling to provide the cells to Monsanto, explaining that Monsanto had unjustly terminated the Research Agreement earlier that year.

138. Dr. Needleman was standing nearby. When Dr. Masferrer reported what Dr. Simmons had said, Dr. Needleman looked over towards Dr. Simmons and loudly proclaimed that he (Dr. Needleman) was not dishonest.

B. Further Misrepresentations By Dr. Needleman

139. In March 1997, Dr. Simmons attended a prostaglandin conference in Cannes, France. Dr. Simmons had not seen or spoken to Dr. Needleman since the 1992 conference in Montreal.

140. Dr. Simmons was eating breakfast in the ballroom of the hotel hosting the conference when Dr. Needleman approached and asked if he could join him.

141. Dr. Needleman began the conversation discussing one of the conference presentations. He then turned the discussion to the subject of COX-2 and represented to Dr. Simmons that he had discovered COX-2 well before Dr. Simmons had and that he had convinced the scientific community of his discovery.

142. Because of Monsanto and Dr. Needleman's systematic fraudulent concealment of the true facts, Dr. Simmons did not have the factual basis, alleged above, to disprove Dr. Needleman's claim. Moreover, Dr. Simmons did not have access to Monsanto's internal scientific documentation that would be needed to expose Dr. Needleman's ongoing deception.

C. Misrepresentations In Patents—A Violation Of 18 U.S.C. § 1962(c)

143. In at least two U.S. Patents assigned to Monsanto, 5,420,343 dated May 30, 1995, and 5,476,944 dated December 19, 1995, Monsanto fraudulently misrepresented that its cell testing systems were constructed using human or murine COX-1 or COX-2 fragments from "Cayman Chemical, Ann Arbor, Mich."

144. As described in Section IX.B, Monsanto's documents reveal that the company's only source of murine COX-1 was Dr. Simmons and Brigham Young University and that the company's only sources of murine COX-2 were Dr. Simmons (April 29, 1991) and Dr. Harvey Herschman of UCLA (August 24, 1992). Monsanto's scientific notebooks make no mention of receiving or using murine COX-1 or murine COX-2 from Cayman Chemical. Further, on June 1, 2010, Dr. Seibert testified that "I don't recall that we received [murine COX-1 and COX-2] coding regions from Cayman Chemical."

145. Monsanto, using the U.S. mail, an interstate carrier, or wire and acting through the COX-2 Project Enterprise, made those false statements to the United States Patent and Trademark Office as part of the scheme to defraud Brigham Young University of its property, including, but not limited to, the Project and Confidential Information.

D. Misrepresentations To The Food And Drug Administration—A Violation Of 18 U.S.C. § 1962(c)

146. On December 1, 1998, Monsanto, acting through the COX-2 Project Enterprise, began making presentations to the Food and Drug Administration (FDA) applying for a special, fast track approval of Celebrex, arguing that the drug was a new class of drugs—a COX-2 selective NSAID. At that meeting, Monsanto presented slides showing Celebrex would block COX-2, but not COX-1.

147. Additionally, Dr. Needleman and Dr. Isakson traveled from Missouri to the FDA offices in Maryland to attend the December 1, 1998 meeting and made statements to the FDA again misrepresenting and concealing Monsanto's true role in the development of Celebrex:

(a) "[W]e watched from the birth of the concept of the COX-2 inhibitors in our laboratories to the fruition and completion of a major clinical trial."

(b) "A second enzyme, a uniquely induced enzyme as we thought in 1990, we named COX-2…"

(c) "Based on the existence of COX-2, we then developed specific COX-2 inhibitors that could go after these rational drug targets but be devoid and spare COX-1 activity."

148. As a further element of the COX-2 Project Enterprise's fraudulent scheme, Monsanto's agents intentionally omitted Dr. Simmons and Brigham Young University's essential contribution to the development of Celebrex and Monsanto's other COX-2 selective NSAIDs. Instead, the members of the COX-2 Project Enterprise misrepresented that Monsanto had independently discovered and identified COX-2, had independently given "birth" to the "concept of the COX-2 inhibitors" such as Celebrex, and had independently developed COX-2 selective inhibitors.

149. Monsanto's statements were intended to mislead hearers and readers that scientists at Monsanto had independently discovered and identified COX-2. These statements were false, but could not be disproved because they were attributed to the research purportedly carried out "in our [Monsanto's] laboratories."

E. Monsanto's Fraudulent Press Releases And Reports—Violations Of 18 U.S.C. § 1962(c)

150. Within a short time after fraudulently terminating the Research Agreement, Monsanto launched a public relations campaign to convince the world that Dr. Needleman had discovered COX-2. When making this claim, Monsanto failed to disclose that it had no COX-2

selective NSAID testing program before its relationship with Dr. Simmons but, instead, was pursuing its search for a steroid-like drug, which to date had been unsuccessful. This public relations campaign is evidenced by, among others, the press releases detailed below.

151. A July 8, 1996, M2 Press Wire release states: "In the 1980s, Dr. Needleman and other researchers pointed the way toward a potential solution when they discovered that PGs [prostaglandins] are produced by two forms of an enzyme called 'cyclooxygenase' – COX-1 and COX-2." The press release quotes Dr. Needleman: "These early results indicate that Celecoxib may be a medication that can relieve pain and inflammation without putting the patient at risk for gastrointestinal damage;" however, the press release does not mention that Dr. Simmons first identified COX-2 and that Monsanto misappropriated the Project. On information and belief, the press release was transmitted interstate by U.S. mail, interstate carrier and/or wire.

152. A 1996 annual report to shareholders, sent interstate by U.S. mail, interstate carrier and/or wire and filed with the Securities and Exchange Commission on March 21, 1997, fraudulently gave credit to Monsanto, not Dr. Simmons, for the discovery of COX-2, stating:

(a) "Phil's research team uncovered two types of cyclooxygenase - - COX-1 and COX-2."

(b) "[Needleman] … formed a molecular pharmacology group to start the hunt for a new inhibitor that would block the inflammation caused by COX-2, while keeping the stomach protection of COX-1. Celecoxib was born from this work..."

(c) "Phil Needleman is one of the few scientists who may see their dreams through - - all the way from the test tube to a human drug proven safe and effective, and approved for use worldwide. His lifetime commitment to solving the puzzle of inflammation could lead [Monsanto] to one of its biggest breakthrough drugs."

153. These statements in the 1996 annual report to shareholders were intended to mislead its readers that Dr. Needleman and other Monsanto scientists, not Dr. Simmons, identified and discovered COX-2, conceived the idea of a COX-2 selective NSAID project, and pioneered the testing system that led to a COX-2 selective NSAID.

154. Other press releases, sent interstate by U.S. mail, interstate carrier and/or wire, continued to reflect Monsanto's ongoing propaganda to misrepresent Dr. Needleman's contribution and cover up Dr. Simmons's contribution.

(a) A November 4, 1996, *Biotechnology News Watch* article entitled "Enzyme Inhibitor has potential as therapy for arthritis pain," stated: "Philip Needleman, a scientist with Searle, who spearheaded research into the COX cascade, discovered that two different COX enzymes were at work in the cascade that produces pain in rheumatoid arthritis."

(b) A December 14, 1998, *U.S. News and World Report* article, entitled "Outfoxing Pathways of Pain" stated: "Philip Needleman, … was instrumental in figuring out in the 1980's that two enzymes help make prostaglandins, dubbed COX-1 and COX-2, and that COX-2 was the driver of the disease's symptoms."

(c) A November 10, 1999, *PR Newswire* article entitled "Celebrex (™) wins Popular Science 'Best Of What's New' Award; Arthritis Treatment Named 'Scientific Advance'" states: "Dr. Needleman first hypothesized the existence of two COX enzymes in the human body: COX-1 helps to regulate normal cell function in the stomach and blood, and COX-2 plays a role in causing pain and inflammation. This discovery led to the development of Celebrex."

(d) A March 10, 2000, *PR Newswire* release entitled "Two Teams Named Winners of Monsanto Science and Technology Award" quotes Dr. Needleman: "It was only the discovery that there are two forms of the COX enzyme - - COX-1 that is present throughout the body and COX-2 that is present at sites of inflammation - - that enabled us to alleviate pain with fewer side-effects. This [Searle] team developed the first selective COX-2 inhibitor, which led to a revolutionary treatment of arthritis for millions worldwide."

(e) A July 11, 2001, statement of Dr. Needleman before the Labor, Health and Human Services, and Education Subcommittee states: "Our studies into the underlying processes that cause the swelling, pain and stiffness of osteo-and rheumatoid-arthritis led to the discovery of a protein-gene called Cox-2 (cyclooxygenase) that is not present in normal stomach or colon tissue but is turned on by tissue injury, inflammation, and various body chemicals released by disease processes."

(f) A February 22, 2002, *PR Newswire* article entitled "Needleman Appointed Science Adviser to Pharmacia Board of Directors and Board Member of Monsanto Company" states: "Needleman is widely credited as the 'father' of the COX-2 inhibitor platform that is revolutionizing the treatment of inflammation-related disease, including Celebrex, the world's leading prescription treatment for arthritis."

(g) A February 22, 2002, *PR Newswire* article entitled "Monsanto Announces Changes to Its Board of Directors" states: "Dr. Needleman has made a number of important contributions in the field of pharmacology, including the discovery of the inflammatory cyclooxygenase-2 (COX-2). This discovery was critical to the development of a new class of arthritis medicines designed to treat the pain and inflammation of osteoarthritis and adult rheumatoid arthritis."

VI. BRIGHAM YOUNG UNIVERSITY BEGINS TO LEARN THE TRUTH

155. Dr. Needleman had represented to investors, elected officials, governmental regulatory agencies, the public, the doctors who would have the power to prescribe selective COX-2 inhibitors, customers, the scientific community, and to Dr. Simmons that Monsanto had independently discovered COX-2 and had conceived the concept of a COX-2 selective NSAID. Brigham Young University and Dr. Simmons did not know, nor reasonably should they have known, that Monsanto developed Celebrex from the Project. As demonstrated below, positions taken by Monsanto in Celebrex litigation, and certain limited discovery, revealed to Brigham Young University that Monsanto misappropriated the Project and used Confidential Information in developing Celebrex.

156. In mid-1998, the pharmaceutical company Merck contacted Dr. Simmons and asked him to testify in Monsanto's patent infringement litigation against Merck. Merck provided Dr. Simmons with publications in which Dr. Needleman appeared to take sole credit for the discovery of COX-2. Merck also told Dr. Simmons that Monsanto's early COX-2 work had been done with clones derived from mouse. This information raised Dr. Simmons's suspicions because some of the clones Dr. Simmons had first provided to Monsanto in 1991 were from mouse.

VII. BRIGHAM YOUNG UNIVERSITY CONFRONTS MONSANTO

157. By summer of 1998, with his suspicions triggered by the conversations with Merck, Dr. Simmons notified Brigham Young University's General Counsel's office who

investigated the matter and then contacted Monsanto's General Counsel's office to inquire about the use of Confidential Information from the Project in developing Celebrex.

158. Despite Brigham Young University's reasonable inquiries, Monsanto continued to fraudulently deny and conceal that it had taken the Project and used Dr. Simmons's Confidential Information in developing COX-2 selective NSAIDs.

A. Correspondence

159. When Brigham Young University contacted Monsanto by interstate telephone call in late 1998, Monsanto denied having ever worked with Dr. Simmons, or in fact, even knowing who Dr. Simmons was. When confronted with the signed Research Agreement, Monsanto admitted to working with Dr. Simmons but continued to deny taking the Project.

160. On December 9, 1999, Brigham Young University's in-house counsel, Eugene Bramhall, wrote to William Ide, then General Counsel for Monsanto, setting forth certain of Brigham Young University and Dr. Simmons's concerns regarding Monsanto's conduct.

161. Five weeks later, in an interstate telephone call with Mr. Bramhall, Monsanto's Joe Bulock fraudulently and categorically denied the allegations in Mr. Bramhall's letter.

162. On March 17, 2000, Dale H. Hoscheit, an attorney at the law firm of Banner & Witcoff, Ltd. wrote Mr. Bramhall, on Monsanto's behalf, a letter sent interstate through the U.S. mail.

163. Mr. Hoscheit's letter again denied Mr. Bramhall's allegations and implications, claiming:

(a) Monsanto scientists "… were not successful in obtaining meaningful replication [of Simmons's mouse COX-2]."

(b) Monsanto had obtained another mouse COX-2 cDNA construct from a third-party source.

(c) Monsanto did not obtain "an immediate, significant and unique advance" in this area because of Professor Simmons.

(d) It was not until Monsanto modified another mouse COX-2 construct from a third party source in 1992 that it was able to gain meaningful expression and Monsanto's testing with mouse COX-2 was based upon that later effort.

164. On or about March 29, 2000, Brigham Young University's counsel and Dr. Simmons sent Monsanto a letter asking fifteen specific questions. Monsanto never squarely addressed these questions in its May 17, 2000, response sent interstate through the U.S. mail; however, the parties agreed to meet in Skokie, Illinois, June 1, 2000.

165. During the meeting, Monsanto again fraudulently denied having used Dr. Simmons's Confidential Information to screen COX-2 selective NSAIDs in general, or Celebrex in particular. Further, Monsanto gave Brigham Young University limited access to Dr. Seibert's notebooks to demonstrate that it had not used Dr. Simmons's research and tools in developing Celebrex. However, Dr. Seibert's notebooks demonstrated the opposite. Dr. Seibert's notebooks evidenced that Monsanto had extensively and successfully used Dr. Simmons's clones. Monsanto refused Brigham Young University and Dr. Simmons's access to the complete notebooks by sealing parts with large metal clips. Monsanto fraudulently misrepresented that the clipped portion related to other, unrelated, confidential projects. In fact, Brigham Young University later discovered that the clipped pages contained the result of Monsanto's NSAID testing for COX-2 selectivity.

166. An August 31, 1992 notebook entry by Dr. Seibert revealed that Monsanto had tested the COX-2 clones of a UCLA researcher (Dr. Harvey Herschman) without success. (Dr. Herschman had published a separate discovery of COX-2 after Dr. Simmons.) The next entry, made on September 3, 1992, indicated that Dr. Seibert planned to continue the work with its REDACTED Dr. Simmons suspected, but did not know it at the time of

the Skokie meeting, that Monsanto had no mCOX-1 or mCOX-2 clones of its own. Dr. Simmons further suspected, but did not know at the time of the Skokie meeting, that Dr. Seibert's reference to Monsanto's REDACTED clones was a reference to Dr. Simmons's clones. And the remaining entries in Dr. Seibert's notebooks were clipped so that Dr. Simmons would not read them.

167. Dr. Simmons confronted Dr. Seibert with what he had seen in her notebooks. However, continuing the pattern of fraudulent concealment, Dr. Seibert emphatically stated that Dr. Simmons's clones had not worked and said that Dr. Simmons's clones had led to "18 months of failed experiments."

B. Tolling Agreement And Mediation

168. In June 2000, Brigham Young University was alerted to Monsanto's fraudulent concealment and investigated further. As the intricate layers of Monsanto's deceptions started to come to light, Brigham Young University only then began to understand the fraud and massive financial harm Monsanto had inflicted. However, as set forth in this First Amended Complaint, Brigham Young University and Dr. Simmons did not then know, and still do not know, the full magnitude of Monsanto and its successors' fraud. Monsanto and the other Defendants have engaged and continue to engage in a pattern of fraudulent conduct designed to enhance the profits from its COX-2 inhibitors and to protect those profits from legal challenge by concealing Monsanto's misconduct.

169. On May 8, 2001, Brigham Young University and Monsanto entered into a tolling agreement preserving Brigham Young University and Dr. Simmons's claims against the Defendants. Since entering the tolling agreement, Brigham Young University has reasonably attempted to mediate this dispute. That effort has failed.

VIII. COX-2 LITIGATION HAS REVEALED THAT MONSANTO USED DR. SIMMONS'S CONFIDENTIAL INFORMATION TO TEST AND DEVELOP CELEBREX

170. Celebrex was approved for clinical use by the FDA on December 31, 1998, and was launched for sale shortly thereafter in January 1999. Since the launch of Celebrex, Monsanto has been involved in various lawsuits to protect its Celebrex patent and Monsanto has initiated lawsuits to gain rights over Merck's patents.

171. In May 1999, four months after the launch of Celebrex, Merck launched Vioxx, its own COX-2 selective NSAID. Upon Merck's launch of Vioxx, Searle [Monsanto] announced that it was suing Merck worldwide, contending that Vioxx's structure was covered by a class of Monsanto patents on compounds related to Celebrex.

172. In addition to litigation with Merck, Searle [Monsanto] was sued by the University of Rochester on April 11, 2000. The University of Rochester claimed that Celebrex violated a University of Rochester COX-2 related patent. On or about November 5, 1999 the Patent Trademark Office ("PTO") had initiated an interference action between the University of Rochester and Merck who each held patents on the sequence and use of human COX-2.

173. Because Dr. Simmons was an expert in the COX-2 field, and a witness to the history of COX-2, various parties to these lawsuits approached him and asked him to testify. Merck asked Dr. Simmons to testify as an expert in the Searle [Monsanto] v. Merck litigation in the United Kingdom. Additionally, Dr. Simmons was asked to testify as a fact witness in the Rochester v. Searle [Monsanto] litigation and as an expert witness in the Rochester v. Merck patent interference action.

A. The Isakson Statement

174. Through Dr. Simmons's participation in these lawsuits, he received information from Monsanto documents contradicting Monsanto's prior statements made to fraudulently conceal Monsanto's wrongdoing.

175. Dr. Simmons promptly informed the Brigham Young University General Counsel's office; and, around October of 2000, Brigham Young University General Counsel ordered copies of transcripts from Monsanto's litigation against Merck from the United Kingdom.

176. Dr. Simmons was read pages from a signed witness statement and various trial transcripts of Dr. Peter Isakson, a scientist at Searle [Monsanto] and the head of the COX-2 selective NSAID Project. Dr. Isakson had given the statements and trial testimony on August 23, 1999, and October 8 and 11, 1999, respectively. Dr. Isakson made clear in his statement that, before meeting Dr. Simmons, Monsanto was not pursuing a COX-2 selective NSAID project. For example, Dr. Isakson stated:

REDACTED

177. As Dr. Isakson explained, REDACTED

178. Dr. Isakson also stated in his signed witness statement that compounds with NSAID-like activity were REDACTED from Monsanto's Project. Monsanto only screened for NSAID-like compounds so that it could exclude them from its testing systems: REDACTED

179. Dr. Isakson's statements made it clear to Dr. Simmons that Monsanto was not looking for a COX-2 selective NSAID before meeting Dr. Simmons. Monsanto only changed course to pursue a COX-2 selective NSAID after meeting Dr. Simmons and then hid important information from Dr. Simmons and Brigham Young University.

180. Dr. Isakson cryptically testified in his August 23, 1999, witness statement that, in developing Monsanto's cell assays for testing DuP-697: [redacted]

[redacted]

[redacted]

181. [redacted] is an intentionally deceptive rewriting of history. Only after collaborating with Brigham Young University was Monsanto in possession of the Confidential Information (including biological materials) necessary to identify cell lines that produce only COX-1 or only COX-2. For example, human fibroblast cells used in Monsanto's cell based assays were first characterized for COX-2 expression using probes generated from Dr. Simmons's COX-2 clone beginning as early as June 1991.

B. The Rochester Litigation

182. Searle [Monsanto] contradicted itself in its litigation against the University of Rochester. For example, in briefs that the University of Rochester filed on September 5, 2001 in support of its motion to compel Searle to produce documents, Searle [Monsanto] claimed that "Brigham Young's scientists were the first to identify methods of treatment using selective Cox-2 inhibitors.…" Thus, upon information and belief, Searle [Monsanto] had taken the position in the Rochester litigation that Dr. Simmons was the first to identify COX-2 and its potential treatments.

183. For the first time, this information gave Dr. Simmons a reasonable basis for knowing that Monsanto's statements regarding Monsanto's supposed pre-existing COX-2 NSAID discovery program were fraudulent.

184. Dr. Simmons and Brigham Young University learned of the Isakson statement in approximately 2000. Dr. Simmons and Brigham Young University learned of the information from the University of Rochester litigation no earlier than 2004.

IX. DR. SIMMONS AND BRIGHAM YOUNG UNIVERSITY ARE VICTIMS OF A MULTI-FACETED FRAUD PERPETRATED BY THE DEFENDANTS IN ORDER TO GENERATE AND PROTECT COX-2 PROFITS

185. Since filing their original complaint, Dr. Simmons and Brigham Young University have learned that Defendants' fraud is much broader in scope and duration—amounting to a violation of 18 U.S.C. § 1961, *et seq*. The description of the Defendants' broader fraud overlaps with the chronology described above. Though Dr. Simmons and Brigham Young University have attempted to avoid repetition, some is necessary to supply context to the additional facts described below.

186. When they filed their original complaint, Dr. Simmons and Brigham Young University did not understand that in 1991 Monsanto/Searle was desperate to find a new hit drug.

187. As Dr. Simmons and Brigham Young University have now learned, in 1991, before meeting Dr. Simmons, Monsanto and Searle had, according to former Searle CEO Richard DeSchutter, been [redacted] As DeSchutter explained at a November 1998 Celebrex launch, despite Searle's [redacted] when [redacted] Dr. Needleman's DIP project to discover a steroid-like solution to pain and inflammation was not yielding results. And, according to DeSchutter, [redacted]

188. During the time period described in this First Amended Complaint, Monsanto remained highly motivated to regain what it perceived as its lost stature in the pharmaceutical business.

189. To regain its stature, Monsanto wanted all of the tremendous profits that Dr. Simmons and Brigham Young University's Project promised.

190. Therefore, Monsanto organized the informal association of entities and individuals described below.

A. The COX-2 Project Enterprise

191. Monsanto called its project to develop a COX-2 selective NSAID the "COX-2 Project." Here, Brigham Young University and Dr. Simmons call Monsanto's informal association of entities and individuals the "COX-2 Project Enterprise."

192. The COX-2 Project Enterprise began in April 1991 as the lawful association between Brigham Young University and Monsanto, among other things, for the purpose of developing and marketing a COX-2 selective NSAID.

193. At the time of the collaboration, Brigham Young University did not know that Monsanto also had two illicit and secret purposes for the COX-2 Project Enterprise: (i) violating 18 U.S.C. § 1341 and 18 U.S.C. § 1344 to obtain the technology and information necessary to develop and market a COX-2 selective NSAID and (ii) violating 18 U.S.C. § 1503 to protect its profits from legal challenge.

194. In fact, though Brigham Young University discovered certain parts of the COX-2 Project Enterprise's fraudulent scheme during the investigation that led to the filing of its original complaint, the University learned of other parts of the COX-2 Project Enterprise's fraudulent scheme since filing its original complaint.

195. Brigham Young University still does not know whether Monsanto always planned to use the COX-2 Project Enterprise for illicit purposes, or whether Monsanto decided to do so some time after April 1991. But it is clear that Monsanto developed its two illicit purposes sometime before Dr. Needleman's March 17, 1992 letter to Dr. Simmons seeking (fraudulently) to terminate the Research Agreement.

196. The membership of the COX-2 Project Enterprise changed over the years, but Monsanto was always a member of the Enterprise. The other members of the COX-2 Project Enterprise included at least Searle, Washington University, Brigham Young University, Dr. Simmons, UCLA, PNAS, Pharmacia, Pfizer, Chandler Chicco Agency, Banner & Witcoff, and Sidley Austin.

197. Some members of the COX-2 Enterprise were complicit with the Defendants. Others, such as Brigham Young University and Dr. Simmons, acted innocently and did not know that the acts they performed on behalf of the COX-2 Project Enterprise were essential components of a complex scheme organized and directed by the Defendants to repeatedly violate 18 U.S.C. §§ 1341, 1344, and 1503.

198. To assist the Court, Brigham Young University and Dr. Simmons provide a chart of certain identified members of the COX-2 Project Enterprise.

Name of Member	Date of Entry	Date of Exit	Culpable/ Innocent	Role
Monsanto/ Searle ("Monsanto")	Along with BYU/Simmons, Original member; April 1991	Via Pharmacia merger and Pfizer acquisition, still a member	Culpable	Participant in each phase of the COX-2 Project Enterprise: development, marketing, litigation

Name of Member	Date of Entry	Date of Exit	Culpable/ Innocent	Role
BYU/Simmons	Along with Monsanto, Original members; April 1991	As of Research Agreement termination (March 23, 1992 or later)	Innocent	Provided the COX-2 Project Enterprise with the PROJECT, CONFIDENTIAL INFORMATION, and critical marketing advantages
Washington University	Masferrer and Seibert (Wash U consultants to Monsanto); April 1991	Still a member through COX-2 discovery representations	Innocent (but Wash U employees, including Seibert and Masferrer, are culpable)	Seibert and Masferrer conducted COX-2 Project Enterprise research at Wash U. Wash U supports Needleman's claim to the discovery of COX-2
UCLA	Keystone Conference; January 1992	Continued to collaborate with Monsanto on COX-2 until unknown date	Innocent	Monsanto used UCLA to hide Monsanto's misappropriation of BYU's CONFIDENTIAL INFORMATION
PNAS	May 1992	PNAS's website still states that Dr. Needleman discovered COX-2	Innocent	Monsanto used PNAS (and other journals) to misrepresent the history of COX-2 inhibitor development
Pfizer	1998	Still a member	Culpable	Fraudulently marketed Celebrex and Bextra and then violated 18 U.S.C. § 1503 to protect profits
Chandler Chicco Agency	1998	Unknown	Innocent	Participated in the fraudulent marketing of Celebrex and Bextra
Banner & Witcoff	March 2000	Unknown	Unknown	Continued fraudulent concealment
Sidley Austin	1997	Still a member	Likely Culpable	Assisted in violations of 18 U.S.C. § 1503

199. Brigham Young University and Dr. Simmons have created a second chart, which is located in Count IX below, summarizing the COX-2 Project Enterprise's violations of 18 U.S.C. §§ 1341, 1343, and 1503.

B. Monsanto Misappropriates Dr. Simmons And Brigham Young University's Confidential Information And Uses It To Find COX-2 Selective NSAIDs

200. Monsanto used the COX-2 Project Enterprise to develop Celebrex, Bextra, and other COX-2 selective NSAIDs by misappropriating Dr. Simmons and Brigham Young University's Project and Confidential Information.

1. Monsanto associates with Brigham Young University to gain access to the University's Project and Confidential Information

201. Instead of searching for a steroid-like drug, the goal of the COX-2 Project (and the COX-2 Project Enterprise) was to misappropriate Dr. Simmons and Brigham Young University's Confidential Information to search for an NSAID that would act directly upon the active site[1] of the COX-2 enzyme that Dr. Simmons had discovered. The Confidential Information misappropriated by the COX-2 Project Enterprise directly resulted in the discovery of Celebrex, Bextra, and other COX-2 selective NSAIDs.

(a) Monsanto learned of COX-2 from Dr. Simmons and Brigham Young University

202. Monsanto and Dr. Needleman's claim to the discovery of COX-2 is fraudulent.

203. At her June 3, 2010 deposition in this case, Dr. Seibert testified that Searle's former CEO, DeSchutter, was wrong when he claimed that [redacted] REDACTED As Dr. Seibert candidly admitted, [redacted] REDACTED with DeSchutter's statement.

[1] An "active site" is the part of an enzyme to which an inhibitor will attach, thereby blocking the enzyme from carrying out its function. In the case of COX-2, NSAIDs like aspirin bind to COX-2's active site, blocking the enzyme's production of prostaglandins.

204. Dr. Seibert also admitted her role in the COX-2 Project Enterprise's cover-up, testifying that [redacted]

205. Monsanto witnesses have made similar admissions in prior litigation. For example, on December 12, 2000, during the Merck Frosst Canada & Co. v. Monsanto Company litigation, Dr. Masferrer testified that [redacted]

206. Drs. Seibert and Masferrer's testimony is consistent with contemporaneous Monsanto documents showing that, prior to collaborating with Dr. Simmons, Monsanto and Dr. Needleman did not know that COX-2 existed. For example, on February 15, 1991, Dr. Roger Wiegand, technical liaison to Searle Strategic Marketing, wrote Dr. Needleman, stating that [redacted] and, if Monsanto could find and target a second COX, [redacted]

207. After beginning the collaboration with Dr. Simmons, Monsanto's understanding, as reflected by its scientific notebooks and other documents, changed. Monsanto's post-Research Agreement documents demonstrate the company's new understanding of COX-1 and COX-2 as separate genes and enzymes—Dr. Seibert and other Monsanto researchers began to refer to "COX-1" and "COX-2" instead of referring to the inducible and constitutive behaviors of COX or simply "COX."

208. For example, by September 10, 1991, several months after Monsanto established the COX-2 Project Enterprise with Dr. Simmons and Brigham Young University, Dr. Seibert knew that [redacted]

REDACTED Dr. Seibert's new knowledge stemmed from the fact that Monsanto had obtained from Dr. Simmons and Brigham Young University, through the Research Agreement, Confidential Information including the REDACTED As described below, Monsanto, through the COX-2 Project Enterprise, fraudulently concealed that it had misappropriated the Project and the related Confidential Information, among other ways, by reinventing its pre-Research Agreement knowledge—misrepresenting that Dr. Simmons had merely confirmed what Monsanto had already found.

(b) Monsanto obtained Brigham Young University's Confidential Information pursuant to the Research Agreement

209. After Brigham Young University and Dr. Simmons filed their original complaint, they learned new facts about Monsanto's use of the Project and Confidential Information.

210. Testifying in the University of Rochester v. G.D. Searle & Co., et al. litigation on January 17, 2002, Dr. Seibert admitted collaborating with Brigham Young University and admitted conducting experiments with the University's Confidential Information: REDACTED

211. Monsanto's documents corroborate Dr. Seibert's testimony and further demonstrate Monsanto's extensive use of Confidential Information obtained from Brigham Young University, including the COX-1 and COX-2 clones, antibodies, and sequences, to accomplish essential steps on the road to the development of its COX-2 selective NSAIDs.

212. For example, on September 10, 1991, Dr. Seibert wrote a Monsanto colleague, Scott Hauser, stating that Monsanto wanted to REDACTED its new mouse REDACTED cDNA to REDACTED Among other things, expressing COX-1 and COX-2 cDNA (causing the COX-1 and COX-2 enzymes to make

prostaglandins) would allow Monsanto to create REDACTED to test NSAIDs for COX-2 selectivity. To help, Dr. Seibert instructed Hauser to use REDACTED The cDNA comparisons that Dr. Seibert provided to Hauser came from Dr. Simmons as indicated by the Brigham Young University fax header.

213. To create additional testing assays, Monsanto used Dr. Simmons and Brigham Young University's clones and antibodies to determine that certain cell lines and tissues could be made to produce only COX-1 or COX-2. As Dr. Simmons conceived and communicated to Monsanto, those cell lines and tissues could then be used to test compounds for selectivity of COX-2 over COX-1.

214. Only the discovery of COX-2 and tools to identify it allowed Monsanto to characterize certain cell lines or tissues as producing only COX-1 or COX-2 in order to test compounds for COX-2 selectivity. And a June 1998 Monsanto document states that Dr. Masferrer used COX-2 specific antibodies—which were first supplied by Dr. Simmons and Brigham Young University—to develop its "critical" cell based assays:

> Dr. Masferrer, using specific antibodies generated against COX-1 and COX[-]2, characterized and developed specific cellular assays to screen for COX-2 selective inhibitors. The availability of this assay was critical to the initial testing scheme and the success of the Project. This effort resulted in the discovery of several chemical leads after testing more than 1200 compounds.

215. Monsanto was also actively using Dr. Simmons and Brigham Young University's other Confidential Information.

216. For example, on or about 18 September 1991, Dr. Seibert sent Dr. Needleman an email stating that REDACTED The scientific notebooks of Dr. Seibert and Monsanto researcher Kathleen

Leahy demonstrate Monsanto's use of [redacted] which are useful for, among other things, compound testing.

217. Pfizer also used Dr. Simmons and Brigham Young University's comparison of the amino acid sequences of COX-1 and COX-2. On March 9, 1992, Dr. Masferrer emailed Monsanto scientist Steve Adams requesting peptides for the creation of antibodies specific for COX-1 and COX-2, explaining [redacted] Attached to the email were several pages of amino acid sequence comparisons, one of which bears a Brigham Young University fax header dated July 16, 1991.

218. Most importantly, however, Monsanto used the totality of Dr. Simmons and Brigham Young University's Confidential Information and Project to gain the scientific understanding necessary to successfully search for a COX-2 selective NSAID.

(c) In violation of the Research Agreement, Monsanto shared Brigham Young University's Confidential Information with the COX-2 Project Enterprise

219. Monsanto brought in Washington University as part of the COX-2 Project Enterprise from April to August 1991—though, as stated above, Washington University did not know that the Defendants were using the Enterprise to engage in a pattern of activity described in 18 U.S.C. § 1961(1).

220. For the COX-2 Project Enterprise's first months, until July 31, 1991, Dr. Seibert was a Washington University employee, but worked for Monsanto through a consulting agreement. On information and belief, Dr. Masferrer was also a Washington University employee working for Monsanto under a consulting agreement.

221. Unbeknownst to Brigham Young University and Dr. Simmons, Monsanto, in violation of Research Agreement Article 4, shared Confidential Information with its other collaborators.

222. For example, on October 29, 1991 and November 25, 1991, Dr. Needleman offered to send Dr. Simmons and Brigham Young University's antibodies and cDNAs for COX-1 and COX-2 to Amiram Raz, a visiting professor at Washington University. Dr. Raz was working on DIP research with Dr. Needleman. As Dr. Needleman described to Dr. Raz, Dr. Simmons and Brigham Young University's clones and antibodies would [redacted]

[redacted]

223. On information and belief, Monsanto also shared Dr. Simmons and Brigham Young University's mouse COX-1 and mouse COX-2 clones with Washington University researcher Dr. Aubrey Morrison.

2. Before Monsanto terminated the Research Agreement, the COX-2 Project Enterprise had successfully tested COX-2 selective inhibitors

(a) DuP-697

224. Brigham Young University and Dr. Simmons have now learned additional facts showing that their Project and Confidential Information caused Monsanto to identify DuP-697 as a lead compound and convinced Monsanto that it could develop a COX-2 selective NSAID.

225. In a January 14, 2000 memorandum describing certain highlights from the COX-2 Project, Dr. Needleman wrote that, after Keystone, Monsanto had obtained two critical contributions—a testing system and lead compounds:

[redacted]

226. Similarly, on February 6, 1992 Monsanto researcher Kathleen Leahy e-mailed other Monsanto researchers explaining that [redacted] REDACTED by the identification of DuP-697 as a potentially COX-2 selective compound—a finding that required the Project and Confidential Information.

227. The fact that DuP-697 was not useful to Monsanto without Dr. Simmons's contributions is confirmed by the fact that, before meeting Dr. Simmons, a Monsanto chemistry group led by John Talley had investigated DuP-697, which had been described in U.S. Patent No. 4,820,827 in 1989 and then in 1990 in a scientific article by Dr. K.R. Gans, but were unable to use the compound for drug development because, before collaborating with Dr. Simmons, they lacked the critical Confidential Information necessary to develop a drug that could target the yet undiscovered COX-2 enzyme.

(b) Monsanto begins testing NSAIDs for COX-2 selectivity

228. Files belonging to Dr. Seibert, which Pfizer withheld for the first three years of this litigation, contain a sub-file labeled with Dr. Needleman's name showing that by February 20, 1992—a month before terminating Brigham Young University—Monsanto had tested at least 16 compounds for COX-2 selectivity using the COX-1 and COX-2 two-cell assay strategy Dr. Simmons had brought to Monsanto. After testing the compounds it had sitting on the shelves, Monsanto began making and testing new compounds.

229. On 3 March 1992, Monsanto chemist Len Lee was able to replicate DuP-697 from its reported chemical structure.

230. Only days after making it, on March 6, 1992, Monsanto screened DuP-697 against the newly-characterized cell based assay using Confidential Information and determined that DuP-697 is selective for COX-2.

231. A March 24, 1992 e-mail from Dr. Seibert to Dr. Needleman, sent shortly after Dr. Needleman's March 17 and March 23 letters to Dr. Simmons, states that tests of DuP-697 [redacted] Dr. Seibert's e-mail also reports that [redacted]

232. John Talley's Monsanto chemistry group got a second opportunity to work with DuP-697 after Talley joined Monsanto's COX-2 Project in 1992. Talley testified, on October 19, 2000 in another litigation, that [redacted] Talley has further testified that he believes Monsanto understood that DuP-697 is a COX-2 selective inhibitor before others because Monsanto [redacted]

3. Monsanto brings Dr. Herschman and UCLA into the COX-2 Project Enterprise in order to conceal the misappropriation of Dr. Simmons and Brigham Young University's Confidential Information

233. Monsanto needed a plausible alternate source of COX-2 clones in order to conceal its use of Dr. Simmons and Brigham Young University's Confidential Information.

234. By March 24, 1992, Monsanto had a commitment from UCLA's Dr. Herschman to provide an alternate mouse COX-2 clone. On or before that time, UCLA joined the COX-2 Project Enterprise. Like Brigham Young University and Washington University, UCLA did not know that the Enterprise was being used by the Defendants to repeatedly commit activities described in 18 U.S.C. § 1961(1).

235. A March 24, 1992, e-mail from Dr. Seibert to Dr. Needleman states that [redacted] Monsanto had figured out a way to cover up its use of Dr. Simmons and Brigham Young University's confidential mouse COX-2 clone—Monsanto would redo its work with the mouse COX-2 clone

of another researcher, Dr. Harvey Herschman of UCLA. As Dr. Seibert's e-mail explains [redacted]

[redacted] REDACTED

236. But Monsanto did not actually obtain Dr. Herschman's mouse COX-2 clone until August 24, 1992. Neither did Dr. Herschman provide Monsanto with a mouse COX-1 clone, COX-2 specific antibodies, or the other critical Confidential Information provided by Brigham Young University. It is undisputed that Monsanto used Brigham Young University and Dr. Simmons's confidential mouse COX-1 clone for the purpose of furthering its own drug development program.

237. Based on notations in Dr. Seibert's notebooks and certain unexplained data, Monsanto may have been unsuccessful in working with Dr. Herschman's clones and, therefore, may have continued to use Brigham Young University and Dr. Simmons's mouse COX-2 clone to accomplish certain critical elements of the COX-2 Project Enterprise, such as establishing recombinant compound testing assays.

238. In the alternative, Monsanto used Dr. Herschman's clones to redo the work that had already been done with Brigham Young University's Confidential Information in order to conceal its theft of the Project and the Confidential Information. According to Dr. Needleman and Monsanto, every additional day of R&D costs $10,000,000 in lost sales. Hence, each day that the COX-2 Project Enterprise wasted by waiting for Dr. Herschman's clone and then redoing previous research with Dr. Herschman's clone cost $10,000,000.

239. Examples of Monsanto's likely use of Dr. Simmons and Brigham Young University's mouse COX-1 and COX-2 clones are described below.

4. Monsanto and the COX-2 Project Enterprise continued to use Dr. Simmons and Brigham Young University's Confidential Information after terminating the Research Agreement

240. A Monsanto 35mm slide (the "Blue Slide") which, according to Dr. Seibert, was created in mid-1992 (more than a year after receiving Brigham Young University's Confidential Information and at least several months after terminating the Research Agreement), shows Monsanto's intent to continue to use Dr. Simmons's mCOX-1 and mCOX-2 clone for [redacted] REDACTED

241. As anticipated by the Blue Slide, Monsanto did use Dr. Simmons and Brigham Young University's mouse COX-1 and mouse COX-2 clones to create critical REDACTED systems for drug screening.

242. An internal Monsanto document dated September 9, 1992, which sought [redacted] REDACTED status for the COX-2 Project, shows that Monsanto had working mouse COX-1 and mouse COX-2 clones as of that date. But Monsanto (and its successors) have not provided Brigham Young University with the scientific notebooks that demonstrate the source of the mouse COX-2 clone that Monsanto used to obtain the expression data described in the Pre-Big Ten document.

243. In this litigation, the Defendants claim that the data was obtained using Dr. Herschman's clone. But the scientific notebooks the Defendants cite to support that claim do not show working mouse COX-1 and COX-2 assays or the pharmacological testing described in the Pre-Big Ten document. The proper inference, based on the date of the Pre-Big Ten document and based on the Defendants' failure to produce the supporting scientific notebooks, is that other notebooks withheld by the Defendants would indicate that Monsanto used Dr. Simmons and Brigham Young University's mouse COX-1 and COX-2 clones for these experiments.

244. An August 1993 draft scientific article authored by Drs. Seibert and Masferrer further demonstrates that Monsanto used Dr. Simmons and Brigham Young University's mouse COX-1 and mouse COX-2 clones for REDACTED The draft article explained that Monsanto had removed the coding region of the COX-1 and COX-2 gene and had reengineered the genes to insert them into REDACTED The expression vectors were then introduced into cell systems in order to produce large quantities of COX-1 and COX-2 enzyme and prostaglandins. As Dr. Simmons conceived and communicated to Monsanto in Appendix A to the Research Agreement, "cell lines which express large amounts of either COX-1 [or] COX-2" can be used to, among other things, test compounds for COX-2 selectivity.

245. The procedure described in the draft scientific article for creating the expression vectors was only necessary in order to use Dr. Simmons and Brigham Young University's clones, but would not have been required to use Dr. Herschman's mouse COX-2 clone. The documented use of that procedure, therefore, confirms that the mouse COX-2 clone used for the research described in the draft article was Dr. Simmons and Brigham Young University's—not Dr. Herschman's. Moreover, the draft article states that REDACTED

246. As described below, Monsanto later modified and published the article, but omitted any reference to Dr. Simmons.

5. Monsanto had a patentable COX-2 selective NSAID months after fraudulently terminating the Research Agreement

247. On January 15, 1993 Monsanto applied for a patent on 3,4-diaryl thiophenes, which the application stated were useful as a result of "having antiinflammatory and/or analgesic activity without erosion of the stomach and therefore more effective and safe." Monsanto had actually discovered 3,4-diaryl thiophenes several months earlier.

248. The first written description of 3,4-diaryl thiophenes was made on August 4, 1992 in the notebook of Stephen Bertenshaw, a Monsanto/Searle chemist who was also one of the listed inventors of Celebrex.

249. Thus, before obtaining Dr. Herschman's mouse COX-2 clone, Monsanto had discovered a family of patentable COX-2 selective NSAIDs.

250. Monsanto later filed infringement claims against Merck, claiming that Vioxx infringed Monsanto's 3,4-diaryl thiophene patent. One of those infringement claims was litigated in the English Court of Chancery litigation ("UK Litigation") referenced above.

251. The particular circumstances of the UK Litigation caused Monsanto to argue that the 3,4-diaryl thiophenes patent broadly claims a class of COX-2 inhibitors. On February 4, 2000, Justice Pumfrey, writing for the court, agreed, stating that Monsanto's "contention is correct. The class is presented as a class of compounds which have anti-inflammatory and/or analgesic activity with fewer and less drastic side effects, the reduction in side effects being due to Cox II selectivity …. The whole thrust of the specification is towards Cox II selectivity."

6. Using the *in vitro* assay conceived by Dr. Simmons, Monsanto generates additional COX-2 selective NSAIDs

252. Dr. Simmons contributed the critical Confidential Information necessary to develop the COX-1 and COX-2 testing systems Monsanto used to go from DuP-697 to patentable, COX-2 selective NSAIDs. As described above, Appendix A to the Research Agreement describes the plan to create "expression vectors" with "murine COX-1 and COX-2" provided by Brigham Young University in order to "test as many NSAIDS as we can … for their ability to inhibit … individual COX isoenzymes," COX-1 or COX-2. In other words, Dr. Simmons and Brigham Young University brought Monsanto, as part of the Research Agreement, the plan and tools to test NSAIDs against recombinant, *in vitro* assays.

253. Monsanto's documents and testimony describe the importance of the *in vitro* assay to the development of COX-2 selective NSAIDs.

254. Also underscoring the importance of the *in vitro* assay, on or around December 8, 1999, Monsanto told the Swedish equivalent of the FDA that [redacted]

[redacted] REDACTED

255. Similarly, Dr. Isakson testified before the FDA on December 1, 1998 that the recombinant *in vitro* assay, which required COX-1 and COX-2 clones, was "the foundation for our drug discovery efforts" because that assay was "the one way that we can assess the activity of a compound under identical conditions" on COX-1 and COX-2.

256. On December 1, 2006, Dr. Seibert testified at the trial in the *Teva* litigation that, from 1991 to 1993, Monsanto was "relying on assays that we had in place" to test compounds and design compounds.

257. The importance of biological contributions to the drug development process explains why biologists like Drs. Isakson, Masferrer, and Seibert were named as inventors on COX-2 inhibitor related patents, including U.S. Patent Nos. 5,380,738, 5,719,163, 5,972,986, 6,649,645, 5,633,272, 5,700,816, 5,756,529, and 6,136,839.

258. Monsanto chemists used *in vitro* assay data to modify and improve compounds, resulting in the patented COX-2 inhibitors. On December 6, 2006, Talley testified at the trial in the *Teva* litigation that his team would "try to take the molecule apart bit by bit, change certain parts of it, and see how that would affect that activity" in the *in vitro* assay. Through that process, called structural activity relationships or SAR, Talley testified that Monsanto synthesized "compounds based on the effect that the structural changes in the compounds had on COX-2 selectivity."

259. Using SAR, Monsanto went from DuP-697 to Celebrex, Bextra, and the other patented, COX-2 selective compounds at issue. As described by Talley in a presentation he made at Drew University in New Jersey on or around June 8-12, 1998 titled, *A Case History The Discovery of the Cyclooxygenase-2 Inhibitor Celecoxib*, during "the early phase of [Monsanto's] medicinal chemistry effort we learned several key pieces of SAR information," for example, the "preferred arrangement of the aromatic rings" and that a "methylsulphonyl or simple sulphonamide were very important for activity against COX-2."

260. In the same presentation, Talley described that Pfizer continued to modify compounds using SAR and then "[a]fter considerable experimentation, we found SC-58635, now known as celecoxib."

261. To generate its second generation selective COX-2 inhibitors, like Bextra, and other COX-2 selective compounds, Monsanto simply continued the same process—modifying existing compounds based on data obtained from *in vitro* and *in vivo* assays. As Talley wrote in an article submitted to the Journal of Medicinal Chemistry on November 17, 1999, Monsanto's "continuing efforts to identify inhibitors with greater potency and high specificity for COX-2," ultimately led to "the identification of SC-65872," Bextra.

C. Monsanto Used A Reputable Scientific Journal To Misrepresent The Source Of Its COX-2 Technology—A Violation Of 18 U.S.C. § 1962(c)

262. Around the time that it was fraudulently terminating the Research Agreement, Monsanto, through its Chief Scientific Officer Dr. Needleman, brought the scientific journal PNAS into the COX-2 Project Enterprise in order to misrepresent, without PNAS's knowledge, Monsanto's contribution to the development of COX-2 inhibitors.

263. PNAS is a well-respected scientific journal that is separate and distinct from Monsanto and which did not (and does not) know that it was being used by the COX-2 Project Enterprise.

264. Monsanto was able to exercise control over PNAS (though PNAS did not know it was being controlled) because Dr. Needleman had been elected as a National Academy of Science member.

265. For an article to be proposed for publication in PNAS, the article must be sponsored, or "communicated," by a member of the National Academy of Science, like Dr. Needleman.

266. Also critical to the COX-2 Project Enterprise's control of PNAS (though PNAS did not know it was being controlled), Dr. Needleman, as a member of the National Academy of Science, had the right to choose the reviewers of the articles he submitted for publication.

267. Monsanto, acting through the COX-2 Project Enterprise, was motivated to use PNAS to misrepresent Monsanto and Dr. Needleman's contributions for several reasons:

a. Dr. Simmons and Brigham Young University were less likely to suspect that Monsanto was misappropriating (and then continuing to use) the Confidential Information if Dr. Simmons believed that Monsanto's pre-Dr. Simmons research was more advanced than it actually was;

b. The PTO and FDA would be more likely to treat Monsanto's COX-2 inhibitors favorably if they believed that Monsanto's Dr. Needleman had discovered COX-2 and was the pioneer of the field;

c. Pfizer's potential selective COX-2 inhibitor customers (and their physicians) would be more likely to buy Pfizer's selective COX-2 inhibitors, rather than those

of Pfizer's competitors, if they believed that Monsanto's Dr. Needleman had discovered COX-2; and

d. Monsanto researchers like Drs. Needleman, Seibert, and Masferrer stood to gain financially and stood to gain influence and prestige within the scientific community if they could take credit for the discovery of COX-2.

268. The following are various instances of Monsanto's use of PNAS (though PNAS did not know it was being used) to misrepresent critical facts regarding the development of Monsanto's selective COX-2 inhibitors. Each of the articles described below were sent from Monsanto to PNAS, interstate, by U.S. mail, interstate carrier, or wire.

269. In May 1992, PNAS published an article titled *Endogenous glucocorticoids regulate an inducible cyclooxygenase enzyme*. The article was authored by Drs. Needleman, Masferrer, Seibert, and another Monsanto researcher, Ben Zweifel, and was "contributed by Philip Needleman." Monsanto used the article to misrepresent that there was still some doubt as to the existence of COX-2, and that Monsanto's work was clearing up that doubt: "Our data indicate the existence of a constitutive COX, which is normally present in most cells and tissues and is unaffected by steroids, and an inducible COX, which is expressed only in the context of inflammation in proinflammatory cells …." The article cited to Dr. Simmons article describing his discovery of COX-2, but emphasized Dr. Needleman's earlier work. By emphasizing Dr. Needleman's work, Monsanto continued its still ongoing fraudulent concealment of its wrongful conduct by causing Brigham Young University, Dr. Simmons, and the research community in general to reasonably believe that Monsanto had independently made discoveries necessary to the development of COX-2 selective NSAIDs.

270. In subsequent articles, Monsanto continued to rewrite the history of COX-2's discovery, incrementally aggrandizing Dr. Needleman's role and continuing Monsanto's fraudulent concealment of Brigham Young University and Dr. Simmons's critical contribution to Monsanto's drugs. In April 1994, a group of researchers from Searle Inflammatory Diseases Research including Isakson, Seibert, Masferrer, and Hauser published an article in PNAS titled *Selective inhibition of inducible cyclooxygenase 2 in vivo is anti-inflammatory and nonulcerogenic*. The article was communicated by Needleman and describes that "COX exists in two forms," and describes, generally, the distinction between COX-1 and COX-2. Among seven different publications cited for that proposition, Monsanto made sure that two of its publications, Needleman publications from 1989 and 1990, were the earliest. The article also misrepresented the originator of the hypothesis that COX-2, and not COX-1, is primarily involved in causing inflammation, again citing the 1989 and 1990 Needleman articles as the earliest publication of that critical hypothesis. As Dr. Simmons and Brigham Young University have now discovered, in 1989 and 1990, Needleman did not know that COX-1 and COX-2 existed. The articles also described that Monsanto had "unpublished data" obtained from testing compounds against assays composed of "baculovirus-expressed recombinant murine COX-1 and COX-2 activity *in vitro*." In order to fraudulently suggest that Monsanto researchers had developed the assay by themselves, the article omitted any reference to the fact that, in order to conceive of and create the assay, Monsanto had relied on the Project, Confidential Information including "murine COX-1 and COX-2," and other critical scientific knowledge obtained from Dr. Simmons in order to create the assay.

271. In 1994, Monsanto, through Dr. Needleman, caused PNAS to publish another article, again citing Needleman's 1989 and 1990 articles for "the existence of two forms of

COX." That article, titled *Pharmacological and biochemical demonstration of the role of cyclooxygenase 2 in inflammation and pain*, was published in December 1994, communicated by Needleman.

272. More importantly, however, the December 1994 article contains language that is nearly identical to language contained in the draft article draft article described above in Section IX.B.4. Like the draft, the published version of the article describes Monsanto's creation of recombinant assays with murine COX-1 and COX-2, but removes attribution to Dr. Simmons as the source of mouse COX-1 and COX-2, which was included in the draft article described above. The article states: "[t]he coding regions of mouse COX-1 and COX-2 were subcloned in the baculovirus expression vector pVL-1393 (Invitrogen)." By omitting mention of Dr. Simmons's contributions, the December 1994 article fraudulently suggests that Monsanto used its own mouse COX-1 and COX-2 to create assays to test compounds for COX-2 selectivity, when, in fact, Dr. Simmons and Brigham Young University had provided the critical scientific knowledge and materials, including the mCOX-1 and mCOX-2 clones, that made the development of those assays possible.

273. In addition to its published articles in PNAS, the National Academy of Sciences' website states that "Dr. Needleman has made decisive contributions in four fields of pharmacology." The website further describes one of Dr. Needleman's contributions as "in 1989-1990, [Dr. Needleman] discovered the inflammatory cyclooxygenase (COX-2) …."

274. Monsanto's misrepresentations in PNAS provided the COX-2 Project Enterprise scientific credibility to exclude Dr. Simmons as an inventor and to conceal and obfuscate Monsanto's use of Dr. Simmons's contribution, including the Confidential Information and Project.

D. An Award Nomination For Dr. Seibert Effectively Outlines Dr. Simmons And Brigham Young University's Essential Contribution To The Development Of Celebrex, Bextra, And Other COX-2 Selective NSAIDs

275. After FDA approval and launch of Celebrex in late 1998, remaining members of the COX-2 Project Enterprise received monetary and personal recognition for their work. Pursuant to Monsanto's scheme, Dr. Simmons and Brigham Young University's essential contributions were concealed. Instead, the credit for Dr. Simmons's work went to other members of the COX-2 project enterprise including Drs. Needleman, Seibert, and Masferrer. For example, an internal Monsanto award nomination, created in 1999, describes Dr. Seibert's purported contributions—as described above, each was a key contribution by Dr. Simmons. The nomination document states:

a. "Arguably among [Dr. Seibert's] most significant scientific contributions is her involvement in the original description of the inducible cyclooxygenase, or COX-2."

b. "Dr. Seibert initiated the COX-2 program at Searle/Monsanto in 1991, an effort which led to the identification and successful commercialization of the first COX-2 inhibitor, Celebrex."

c. "The discover[y] and characterization of COX-2 led to the hypothesis that specific inhibition of COX-2 would provide the anti-inflammatory and analgesic effects of NSAIDs without affecting COX-1 and its important physiologic functions."

d. "Dr. Seibert's research extended beyond the fundamental observations made about the COX-2 enzyme, and also embraced the effort to develop compounds that specifically inhibit the inducible COX-2 isoform. Under her initial leadership, Searle initiated a drug discovery program directed at this new molecular target."

e. "Once the COX-2 inhibitor program was officially begun in 1992, Dr. Seibert played a key role in the biological aspects of the Project … she was critical in developing the biological testing scheme for the medicinal chemistry efforts and in choosing compounds for further advancement."

f. "In particular, after cloning and expression of the COX isozymes by the molecular biology group in Monsanto, her laboratory developed the *in vitro* recombinant enzyme based screening assay that provided all of the basic structure activity data for Searle's COX-2 inhibitors. Thus, Karen was key to developing the system that would define selectivity and ultimately select celecoxib as the lead compound."

E. Marketing Misrepresentations To Increase Celebrex Sales—A Violation Of 18 U.S.C. § 1962(c)

276. By 1998, Monsanto entered into a joint venture with Pfizer to market and sell Celebrex—Pfizer joined the COX-2 Project Enterprise. Until Pfizer acquired Pharmacia and Monsanto in 2003, Pfizer was separate, distinct, and unrelated to Monsanto.

277. Pfizer and Monsanto, through the COX-2 Project Enterprise, perpetuated the misrepresentation that Dr. Needleman had discovered COX-2.

278. Around January of 1999, Pfizer (and/or Monsanto) hired an advertising agency, Chandler Chicco Agency LLC, to develop a national marketing program to help promote Celebrex. Chandler Chicco joined the COX-2 Project Enterprise.

279. The COX-2 Project Enterprise's marketing campaign falsely represented that Dr. Needleman—not Dr. Simmons—was the REDACTED of COX-2 so that Pfizer could REDACTED According to a Pfizer public relations plan, this (false) message was to be spread to REDACTED

[redacted]

REDACTED

280. Furthermore, Pfizer documents contain scripts that Pfizer agents could use to respond to assertions by others that might be contrary to Pfizer's REDACTED And one of those anticipated assertions was the assertion that REDACTED Pfizer's suggested response to that assertion was for its agents to ask, REDACTED and then to tell the REDACTED

281. In addition, Pfizer authored or had authored various publications (including but not limited to those described in Section IX.C. above) containing the same misrepresentation about Dr. Needleman as the supposed discoverer of COX-2. Some of those articles were published in scientific journals, others were apparently given directly to doctors, and yet others were used to train Pfizer sales agents. All such publications were designed and intended, in part, to perpetuate the fraudulent story that Dr. Needleman, not Dr. Simmons, was the discoverer of COX-2 and misrepresent the status of Monsanto and Washington University's research prior to Monsanto's collaboration with Brigham Young University. If Dr. Simmons was mentioned at all, he was merely credited with confirming what Dr. Needleman already knew. Along with fraudulently concealing Monsanto's conduct, the COX-2 Project Enterprise's misrepresentation of Dr. Needleman as discoverer also contributed to Pfizer's fraudulent scheme to increase its profits from COX-2 inhibitors by perpetuating the misperception that Dr. Needleman and Searle were the REDACTED of COX-2 research.

F. Marketing Misrepresentations To Increase Bextra Sales—A Violation Of 18 U.S.C. § 1962(c)

282. As part of the same scheme to enhance its COX-2 profits, Pfizer and the COX-2 Project Enterprise fraudulently misrepresented the effective uses of their COX-2 inhibitors.

283. In 2000, Pharmacia acquired Monsanto and prepared to bring the second generation COX-2 inhibitor, Bextra, to market. With its acquisition of Monsanto, Pharmacia joined the COX-2 Project Enterprise and continued and expanded the Enterprise's pattern of activity in violation of 18 U.SC. § 1961, *et seq*.

284. In furtherance of the fraudulent scheme to enhance COX-2 related profits, Pharmacia (and its successor Pfizer), through the COX-2 Project Enterprise, fraudulently marketed Bextra.

285. Federal and state agencies eventually discovered Pharmacia/Pfizer's misconduct, conducted an investigation, and reached a settlement with Pfizer/Pharmacia totaling $2.3 billion dollars.

286. But neither Pfizer nor Pharmacia pleaded guilty. Instead, Pfizer caused its subsidiary, Pharmacia & Upjohn Company, Inc., created on March 27, 2007, after the fraudulent marketing occurred, to plead guilty to the criminal acts performed by the Defendants through the COX-2 Project Enterprise.

287. According to a United States' Sentencing Memorandum, Pharmacia/Pfizer had promoted the sale of Bextra "for unapproved uses and dosages and/or with false and misleading claims of safety and efficacy and without disclosing the FDA's safety concerns." To conduct those activities, Pharmacia/Pfizer acted through the COX-2 Project Enterprise and used the U.S. Mail, interstate carriers, and wire transmissions to conduct an artifice or scheme to fraudulently market Bextra and other drugs.

G. Pfizer's Related Scheme To Fraudulently Enhance Its Profits From Other Drugs—A Violation Of 18 U.S.C. § 1962(c)

288. On March 26, 2010, Pfizer was found guilty of federal RICO violations in connection with the marketing of its epilepsy drug, Neurontin, and was ordered to pay $142 million in damages ($47.3 million trebled).

H. Pfizer, Through The COX-2 Project Enterprise, Obstructs Justice To Protect Its COX-2 Related Profits From Legal Challenge—A Violation Of 18 U.S.C. § 1962(c)

289. To avoid liability for its wrongful acts, the COX-2 Project Enterprise "corruptly … influences, obstructs, or impedes, or endeavors to influence, obstruct, or impede the due administration of justice."

290. Specifically, members of the COX-2 Project Enterprise, including Pfizer and its high-profile outside counsel, use the U.S. mail and wire transmissions to fraudulently conceal their bad acts by misrepresenting the existence of relevant documents that Pfizer, according to the duties imposed by the Federal Rules of Civil Procedure, must produce in litigation. Because the facts described in this section occurred primarily after Pfizer acquired Pharmacia in 2003, the Defendants are referred to jointly as Pfizer for the remainder of this Section.

291. Further, those members of the COX-2 Project Enterprise, "endeavor[] to influence, obstruct, or impede the due administration of justice" by creating a massive document storage facility that allows Pfizer to find documents when Pfizer wants them—such as when seeking regulatory approval—but also allows Pfizer to hide documents—while providing plausible deniability—during litigation. And this massive storage facility was created at a time when Pfizer had a duty to preserve documents relevant to this litigation.

292. Though the Court has sanctioned Pfizer $852,315.80 for some of its discovery misconduct, Pfizer continues to withhold documents. Without those documents, Brigham Young

University cannot fairly try its claims and Pfizer, in exchange for a one-time sanction of less than a million dollars, will not put at risk the billions in profits that it has already improperly kept from Brigham Young University and the billions more that it continues to keep from the University.

1. Pfizer and Sidley Austin misrepresent the existence and availability of relevant documents

293. On information and belief, Defendants first retained the Chicago law firm Sidley Austin LLP in connection with the COX-2 Project Enterprise in or around August 1997 regarding the *Bertenshaw v. Ducharme* Patent Interference No. 103,873.

294. On information and belief, in addition to its discovery misconduct in this litigation, Pfizer has engaged in the same intentional, bad faith discovery misconduct in other COX-2 related litigation such as *Merck Frosst Canada & Co. v. G.D. Searle & Co. and Monsanto Co.*, 1:99CV02620; *University of Rochester v. G.D. Searle & Co., et al.*, 00-CV-6161; and *Pfizer Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, 04-754.

295. Brigham Young University discovered Pfizer's pattern of discovery misconduct during discovery in this litigation.

296. On January 12, 2007, Brigham Young University requested documents from Pfizer related to the Research Agreement and, more broadly, to the Project and related development of Celebrex, Bextra, and other COX-2 selective inhibitors.

297. Pfizer responded to Brigham Young University's requests claiming that, instead of searching its files for responsive documents, Pfizer would rely primarily on its productions in earlier COX-2 related litigations.

298. Specifically, on February 14, 2007, and again on October 22, 2007—attempting to convince Brigham Young University that Pfizer's production from the *Pfizer v. Teva* litigation

was sufficient—Pfizer violated 18 U.S.C. § 1962(c) by misrepresenting that: "All of the documents predating June 1995 that were produced in the Rochester litigation were also produced in the Teva litigation…."

299. Pfizer also represented that the combined productions from the *Teva* and *Rochester* litigations would contain nearly all the relevant documents, according to Pfizer, because the *Rochester* production includes "virtually all technical documents related to COX-2," and because the parties in both *Rochester* and *Teva* had responded to document requests "particularly relevant" to this litigation.

300. However, Brigham Young University subsequently discovered several highly relevant documents that Pfizer had failed to produce as part of the *Teva* production.

301. When Brigham Young University confronted Pfizer and its counsel with evidence of these failures in late 2007, Pfizer continued to make related representations about the expansiveness of its searches and the purported reasons that certain documents had not been produced as part of the *Teva* production. Exhibit B details a portion of those additional representations.

302. For example, on October 22, 2007, Pfizer, through its counsel, represented that the reason Pfizer had not produced more documents related to Dr. Simmons was because "Pfizer was unable to get Dr. Simmons' COX-2 clones to work."

303. Brigham Young University has now learned that Pfizer's representations regarding its production of documents and the usefulness of Dr. Simmons's clones were knowingly false when made and were designed to fraudulently conceal evidence demonstrating Dr. Simmons and Brigham Young University's essential role in the development of Celebrex,

Bextra, and the other selective COX-2 inhibitors. These representations are violations of 18 U.S.C. § 1962(c).

304. For example, Pfizer knowingly removed a whole series of relevant documents from its *Rochester* production before producing the documents to Teva and Brigham Young University. That undisputed fact alone demonstrates that Pfizer and its lawyers knew that their representations—including that all pre-1995 "technical documents" from the *Rochester* production were given to Teva and Brigham Young University—were false. And, based on the high degree of relevancy of many of the removed documents, Pfizer's intentional misrepresentations to Brigham Young University and the Court were made in order to obstruct justice in pending litigation, namely the Teva and Brigham Young University litigations.

305. Additionally, although scientific notebooks are a critical source of evidence in this litigation, Pfizer has failed to produce indices that would identify the scientific notebooks that were assigned to researchers during the critical time period. Without such indices, which are apparently available from Pfizer's computer system and other sources, Brigham Young University has no way of verifying whether Pfizer has produced all the notebooks kept by researchers doing relevant COX-2 related work.

306. After discovering that Pfizer was withholding documents, Brigham Young University filed a motion to compel on January 10, 2008. On March 26, 2008, the Court granted Brigham Young University's motion and ordered Pfizer to "provide a complete production, after a full search for all documents in Defendants' possession, custody or control, responsive to Brigham Young University's First Request for Production of Documents."

2. Pfizer, through the COX-2 Project Enterprise, concealed facts from Brigham Young University by misrepresenting COX-2 scientific data and by violating its own policies and FDA guidelines including by

recreating scientific data years after the fact—violations of 18 U.S.C. § 1962(c)

307. After the Court's Order, Brigham Young University discovered another example of Pfizer's interference with the judicial process through discovery misconduct—a chart (the "Rangwala chart") pasted onto a page of Monsanto researcher Shaukat Rangwala's scientific notebook dated October 6, 1992; the Rangwala chart contains highly relevant mouse COX REDACTED data for which Pfizer has produced no supporting documentation. As described above, COX REDACTED is useful for, among other things, drug testing. The issue is whether Pfizer is hiding data showing that its predecessor, Monsanto, used Dr. Simmons's mouse COX-1 and mouse COX-2 clones to obtain that critical expression data.

308. After Brigham Young University pointed out the lack of support for the Rangwala chart, Pfizer, on August 12, 2008, filed a certification with the Court claiming that the data in Rangwala's chart was not as shown in the official notebook page, but that it was (1) averaged, (2) multiplied, (3) incorrectly recorded with regard to dates, (4) incorrectly recorded with regard to species, (5) incorrectly recorded with regard to the length of the assay, and (6) summed data from other investigators' notebooks that Pfizer did produce.

309. That explanation was designed to convince Brigham Young University and the Court that Pfizer had no additional documents to produce and, more generally, that Monsanto had used Dr. Herschman's mouse COX-2 clone, not Dr. Simmons's. Pfizer's explanations are not scientifically credible.

310. Rangwala's mouse COX-1 data was produced using Dr. Simmons's mCOX-1 clone because, as Pfizer admits, it never had another source for mouse COX-1.

311. Rangwala's mouse COX-2 data also likely resulted from the use of Dr. Simmons's mCOX-2 clone because Pfizer's data does not match the data it generated using Dr.

Herschman's clone and, in one case, because the Herschman data was not available until 16 days after Rangwala inserted the table into his notebook.

312. In an attempt to avoid being sanctioned by the Court, Pfizer and its counsel repeatedly made unequivocal representations to Brigham Young University and the Court that they had investigated the Rangwala chart issue and that Rangwala, Dr. Seibert and the other researchers involved had confirmed Pfizer's story. But again, Pfizer's story turned out not to be true. At their depositions, neither Dr. Seibert nor Rangwala claimed responsibility for the data contained in the Rangwala chart. And contradicting Pfizer's claim that its representations about the source of the Rangwala chart data were supported by interviews of Drs. Seibert and Rangwala, neither of those researchers can confirm where the data actually came from because neither claims knowledge of the origin of the chart itself.

313. The depositions of Dr. Seibert and Rangwala also revealed that the COX-2 Project Enterprise engaged in practices forbidden by Monsanto policy and by FDA regulations of Good Laboratory Practice (GLP) applicable to entities involved in drug development. These forbidden practices include at least the re-creation of scientific notebooks and the failure to have notebooks witnessed and countersigned.

314. On June 23, 2010, Rangwala testified that he kept primary data on loose paper and in spiral notebooks. And then, as late as three years after the original research events took place, Rangwala used those loose papers and notebooks to create official records, this time in official Monsanto notebooks. Rangwala further testified that, after creating those official records years after the fact, he then destroyed his original notebooks and notes by placing them in Monsanto bins for shredding. Because of this practice, he could not testify that the dates of notebook entries were as they were represented. He even testified that the date on which he

purportedly signed and dated the cover sheet acknowledgment that he had read and understood the list of important company notebook policies may not have been actually signed on the date represented.

315. But even that new story does not change the fact that supporting documents for the Rangwala chart are missing. First, Pfizer's suggested data still does not match the Rangwala chart. Second, despite acknowledging his breaches of Monsanto policy, Rangwala testified that he had no reason to believe the data underlying the October 6, 1992 notebook entry was unavailable on that date or was, in any way, inaccurate, contradicting Pfizer's claim that data reflected in the Rangwala chart was created 16 or more days later.

316. Similarly, on June 1, 2010, Dr. Seibert testified that she regularly violated policies by never having her critical COX-1 and COX-2 related scientific notebooks countersigned.

317. These facts demonstrate that, not only will Pfizer make misrepresentations regarding discovery in order to obstruct justice, but will disregard federal regulations regarding research in order to perpetuate misrepresentations to government agencies such as the FDA and PTO.

3. Pfizer's discovery misconduct and related misrepresentations are intentional and violate 18 U.S.C. § 1962(c)

318. Despite Pfizer's continued representations that its production was complete, Brigham Young University continued to find evidence that Pfizer was withholding documents. In an effort to prove that it had complied with its discovery duties, on May 11, 2009, Pfizer submitted 800 pages of Court-ordered affidavits describing its discovery efforts in this litigation.

319. Included among those 800 pages was the May 8, 2009, Affidavit of J. Michael Warner, an assistant general counsel for Pfizer.

320. In his affidavit, Warner disclosed that, despite Pfizer's numerous representations that it had complied with the Court's prior order—which required, among other things, that Pfizer produce all documents in produced to *Rochester*—[redacted] REDACTED and after consulting its Sidley Austin counsel, Pfizer [redacted] REDACTED [redacted] Warner's affidavit contradicted earlier Pfizer representations that even original document collections without bates numbers had been searched for missing documents.

321. Resisting Brigham Young University's demands to review the COX-2 collection, Pfizer and its counsel represented to the Court and to Brigham Young University that reviewing the collection would not uncover any new documents: "[w]e believe everything in there [the COX-2 collection] was produced at least once, probably twice."

322. On August 3, 2009, however, pursuant to Court order, Brigham Young University counsel inspected the collection of documents in Pfizer's in house counsel's office and found, among hundreds of boxes and binders of COX-2-related documents—about 270,000 pages—a particularly relevant, and previously unproduced, group of 3,397 pages associated with Dr. Seibert (the "Seibert file").

323. The very first page of the Seibert file bears the handwritten note, [redacted] REDACTED— Brigham Young University had specifically asked Pfizer for Dr. Seibert's diaries for years, but Pfizer did not produce any. Among other critical documents found in the Seibert file are the September 10, 1991, fax from Dr. Seibert to Scott Hauser (described in Section IX.B.1 above)—a handwritten note describing that, by January 1992, Dr. Seibert had successfully made clones incorporating Dr. Simmons's mCOX-1 and mCOX-2 cDNA—the sub-folder (also described in Section IX.B.2 above) demonstrating that Monsanto had successfully tested (by

January 31, 1992) COX-2 inhibitors before fraudulently terminating the Research Agreement, and research notes showing that Dr. Seibert had unsuccessfully spent the two years prior to meeting Dr. Simmons trying to discover a second COX gene and enzyme.

324. Brigham Young University immediately asked Pfizer to indicate where in its previous production it had provided Brigham Young University with the Seibert file.

325. Several months later, on November 19, 2009, Pfizer admitted that it had never produced the Seibert file to Brigham Young University.

326. Pfizer further claimed that it had produced the Seibert file in the *Rochester* litigation, but that, "inadvertently," Pfizer failed to produce thousands of pages from the *Rochester* production and, instead, had misrepresented many of the pages it was now producing from the *Rochester* production "as gaps."

327. These "gaps" were documents from the *Rochester* production that Pfizer told Brigham Young University on May 27, 2008, "simply never existed."

328. This new information from Pfizer began months of investigation by Brigham Young University into Pfizer's discovery practices. That investigation uncovered evidence that Pfizer's discovery-related misrepresentations were not mere inadvertence, as Pfizer and its counsel claim, but intentionally fraudulent and intended to violate 18 U.S.C. § 1962(c) by concealing critical documents, including the Seibert file.

329. That evidence, some of which is briefly summarized below, shows that Pfizer's November 19, 2009, excuse for failing to produce the critical Seibert file—"We believe that the contractors and paralegals … inadvertently overlooked these ranges"—is knowingly false:

a. Pfizer and its Sidley Austin counsel failed to produce the same Seibert file in the *Rochester* litigation until nine months after the University had deposed Dr.

Seibert. When Pfizer finally produced the documents to the University, Sidley lawyer Lisa Schneider explained in a letter that Pfizer had withheld the Seibert file because they had been lost in an "abandoned file cabinet;"

b. Pfizer's lawyers possessed this October 31, 2002, letter transmitting the Seibert file to Rochester in their file at the same time Pfizer was representing through these lawyers to Brigham Young University that it could not locate this very gap in the *Rochester* production and, therefore, it mostly likely did not exist;

c. When questioned about it at her July 1, 2010 deposition Dr. Seibert had [redacted] REDACTED of facts regarding finding a box of her documents in an abandoned file cabinet;

d. The box containing the Seibert file has the *Rochester* Bates-range for the Seibert file printed right on the outside of the box. This is the Bates-range that Pfizer represented to Brigham Young University on May 27, 2008, as describing documents that "simply never existed," and to the Court and to Brigham Young University on May 27, 2008, as documents that REDACTED and on July 18, 2008, as documents that possibly REDACTED

e. The Seibert file metadata—information about the box from Pfizer's electronic database that explains the box's contents and its history—show that the file had been stored in Sidley's Chicago office from at least April 2004 to October 16 2008;

f. Pfizer and its Sidley counsel had at least two copies of the Seibert file in their possession at the same time they represented the missing gap in the *Rochester* production could not be found and, therefore, "never existed in the first place."

330. In light of the foregoing, Pfizer's explanation of mere inadvertence is not credible. Pfizer has intentionally sought to obstruct evidence by withholding critical documents.

4. Pfizer created PRSC to hide documents further violating 18 U.S.C. § 1962(c)

331. Pfizer maintains an extensive and diverse collection of documents relevant to the development, regulatory review, and marketing of its drugs.

332. In 2006, five years after the parties to this dispute signed a tolling agreement and Pfizer had a duty to preserve documents, Pfizer created a centralized storage facility for its documents, Pfizer Records Service Centre ("PRSC"). According to Pfizer, a central purpose of creating PRSC relates to document production for litigation.

333. To fill PRSC, Pfizer has gathered documents from its subsidiaries regardless of where the documents were created, who created them, or which of Pfizer's many drugs the documents relate to. That process resulted in the gathering up of documents associated with Monsanto's development of the COX-2 selective NSAIDs at issue. So documents relevant to this case were lumped in with hundreds of millions of pages of irrelevant documents.

334. As of July 2009, PRSC contained approximately 500,000 boxes, which Pfizer estimates contain about 1.5 billion pages of documents.

335. Because the boxes are not stored by category, the only way Pfizer can find documents in PRSC is by searching a database called "Preserve."

336. Preserve, though, does not contain searchable text from the documents stored in PRSC. Rather, Preserve contains "metadata," or, in other words, descriptions of documents.

337. Pfizer's designated 30(b)(6) witness, Kathy Owen, testified on June 10, 2008 that "what's in the database [Preserve] is dependent upon the information that somebody put in at the time they archived the record."

338. The problem is that the Preserve metadata is created by Pfizer employees—or whoever else happens to send the record to PRSC—without any supervision or adequate policies in place to ensure that the metadata is accurate or complete.

339. At her deposition, Ms. Owen admitted that "there is a chance that people could archive information without descriptive – sufficient descriptive information that you would not be able to locate it."

340. The metadata for the critical Seibert file, which, as described above, Pfizer withheld from Brigham Young University for the first three years of this litigation, demonstrates that Pfizer's metadata is, at least in the case of that critical group of documents, virtually unsearchable. That is because the Seibert file metadata contains abbreviations, shorthand descriptions of large categories of documents, and doesn't even list Dr. Seibert's name:

> Vandy Stuff; Rat Infusion; Rat Colon; Rat Stomach; Laboratory Experiments in Biochemistry for Graduate Students 1983, Department of Biochemistry Vanderbilt University; Stenographic Note Book, KS Diary 2; Screening Group Meeting; COX Exec 1994 Chem Notes; Chem Review Skokie 1994; Arem Mtg 1995; Chem Mtg; Chem Review St. Louis; Biochem Methods; PN-lab Presentation; More Lab Talks; PLT-2; Merke Lab Mtg

341. Further, despite its massive size, PRSC is incomplete. For example, Pfizer's IT department has control over electronic data. Other Pfizer documents are housed at individual research facilities (such as the Chesterfield facility where much of the research at issue in this case took place), in its legal department, and at its outside lawyers offices. Further, as evidenced by the Seibert file's history, documents from decades earlier can be moved into (or out of) Preserve at any time. That unregulated movement is another way through which Pfizer can use PRSC to hide documents.

342. For example, on January 21, 2010, Pfizer represented to Brigham Young University and the Court that [redacted]

REDACTED Thus, it appears that Pfizer has not even searched these REDACTED now buried in PRSC.

343. Pfizer uses Preserve searches of PRSC to create the illusion that it is performing "Herculean" searches. If Pfizer's Preserve searches fail to locate a document, Pfizer insists that the document must not exist or simply cannot be located. But Pfizer knows that Preserve searches are not reliable and can be manipulated to effectively hide documents.

344. Further, by sending documents to PRSC after its duty to preserve documents arose, Pfizer violated its duty by concealing and spoliating relevant documents.

345. Pfizer's use of PRSC to hide documents and obstruct justice is part of the COX-2 Project Enterprise's scheme to fraudulently enhance its profits and to protect those profits from legal challenge.

346. On information and belief, Pfizer also uses the PRSC to conceal evidence in other pending litigations.

5. Pfizer further obstructed justice by using misrepresentations to withhold relevant biological materials and then spoliated a relevant sample

347. Pfizer and its lawyers made another series of related misrepresentations in order to conceal biological materials that demonstrate the COX-2 Project Enterprise's use of Dr. Simmons and Brigham Young University's Confidential Information.

348. In addition to requesting relevant documents, on January 12, 2007, Brigham Young University requested that Pfizer produce relevant biological materials.

349. Brigham Young University repeatedly followed up with Pfizer to get responsive materials.

350. Eventually, on October 9, 2007, Ms. Schneider wrote to Brigham Young University on behalf of Pfizer misrepresenting that "Pfizer has to date been unable to locate any

biological materials requested in plaintiffs' document requests." This was a violation of 18 U.S.C. § 1982(c).

351. After Brigham Young University continued to press the issue, Pfizer changed its story. Ms. Schneider wrote Brigham Young University on January 7, 2008 claiming that Pfizer had used up Brigham Young University's biological materials during the parties' mediation:

> Pfizer did have certain biological materials as of the time of the mediation. However, Pfizer had only very small quantities at that time and those materials were utilized to obtain sequence data during the mediation.

352. Pfizer changed its story again. Then, to minimize the importance of Dr. Simmons's contribution, Pfizer told this Court on March 19, 2008, that Pfizer "discarded" Dr. Simmons's biological materials because they did not work:

> It's our view that Dr. Simmons' clones didn't work, so there was a minimal amount of research with them and then they were discarded.

353. A list of Pfizer's additional biological material-related misrepresentations is attached as Exhibit C.

354. On May 21, 2008, despite Pfizer's misrepresentations that it could not locate responsive materials and approximately two months after the Court ordered Pfizer to produce all responsive material, Pfizer identified eight vials of biological materials whose labels include "Simmons."

355. Pfizer also identified over 295 more vials not specifically labeled "Simmons," but responsive to Brigham Young University's requests because they contain COX-1 or COX-2 biological materials, including mouse COX-1 and mouse COX-2.

356. For example, one of the vials that Pfizer identified, labeled "Simmons mouse COX1/COX2," appears, according to Pfizer's notebooks, to have been a chimera.

357. In Greek mythology, a chimera was a creature composed of parts from multiple animals: the head of a goat on the body of a lioness with a tail ending in a snake head. In science, the term chimera is used to describe the scientific engineering of something into a product that does not exist in nature. For example, scientists will sometimes construct a chimeric clone out of part of a COX-1 clone and part of a COX-2 clone in order to study their properties more closely.

358. The fact that Pfizer created a chimera out of Dr. Simmons's COX-1 and COX-2 clones indicates that Dr. Simmons's biological material worked, and that Pfizer was using them heavily to further its understanding of COX-1 and COX-2 in its work toward developing Celebrex.

359. On January 14, 2009, in a footnote on page four of its letter, Pfizer indicated: "We have been informed that in the process of moving samples to a more secure freezer for continued storage, it was discovered that two of the samples originally located are now unaccounted for. Pfizer is continuing to search for these two missing samples, which were labeled 'pMON2297 hCOX2' and 'Simmon mouse COX1[/]COX2.'"

360. On February 16, 2009, Pfizer described its spoliation of the chimera: [redacted]

[redacted]

361. Pfizer's attempts to "impede the due administration of justice" by withholding and spoliating biological materials are predicate acts committed by the COX-2 Project Enterprise under 18 U.S.C. § 1503.

X. CLAIMS FOR RELIEF

COUNT I
(BREACH OF WRITTEN CONTRACT)

362. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the First Amended Complaint as though set forth in their entirety herein.

(a) ¶ 1.3

363. Pursuant to ¶ 1.3 of the Agreement, among other things, Monsanto agreed that the Project and all work assigned would be carried out under the direction of Dr. Simmons, the Project Director. The Project included the search for a COX-2 selective NSAID with the use of Confidential Information.

364. Monsanto breached the contractual duties specified above when it usurped the Project and began conducting research outside of Dr. Simmons's direction.

(b) ¶ 1.6

365. Pursuant to ¶ 1.6 of the Agreement, Monsanto agreed, among other things, to furnish prostaglandins, NSAIDs and consulting services.

366. Monsanto breached the contractual duties specified above when it failed to furnish prostaglandins, NSAIDs, or consulting services to Dr. Simmons and Brigham Young University. For example, Monsanto failed to provide DuP-697 or its derivatives to Brigham Young University even though they had the greatest potential for being COX-2 selective NSAIDs. Monsanto also failed to provide consulting services that would have promoted Monsanto and Brigham Young University's cooperative effort to achieve the Agreement's objectives.

(c) ¶ 3.1

367. Pursuant to ¶ 3.1 of the Agreement, Monsanto agreed, among other things, that title to all discoveries and inventions, whether or not patentable or patented would be determined as follows:

368. If one or more Brigham Young University personnel only are inventors, title shall belong to Brigham Young University;

369. If one or more MONSANTO personnel only are inventors, title shall belong to MONSANTO; and

370. If one or more personnel of Brigham Young University and MONSANTO are joint inventors, title shall belong jointly to Brigham Young University and MONSANTO.

371. Monsanto breached the contractual duties specified above when it failed to inform Brigham Young University of its title to patentable discoveries resulting from the Project in which Brigham Young University was the inventor or, at a minimum, a joint inventor.

(d) ¶ 3.3

372. Pursuant to ¶ 3.3 of the Agreement, among other things, Monsanto owed Brigham Young University a duty to notify Brigham Young University of research results obtained from the Project that were patentable and indicate its interest in a license from Brigham Young University under such prospective patents.

373. Monsanto breached its contractual duties to Brigham Young University by failing to notify Brigham Young University of the patentable research results obtained from the Project.

(e) ¶ 3.4

374. Pursuant to ¶ 3.4 of the Agreement, Monsanto owed Brigham Young University a duty to negotiate in good faith the terms and conditions of a royalty-bearing license agreement with a right to sublicense on all patented inventions developed in the Project.

375. Furthering its prior breach of failing to notify Brigham Young University of patentable results from the Project, Monsanto breached its contractual duties to Brigham Young University by failing to negotiate a royalty for Brigham Young University on such patented inventions resulting from the Project.

(f) ¶ 3.5

376. Pursuant to ¶ 3.5 of the Agreement, Monsanto owed Brigham Young University a duty to allow Brigham Young University to designate, at its sole option, a patent attorney, either from Monsanto or in private practice, to file and prosecute a patent application with regard to any patentable research results obtained from the Project.

377. Monsanto breached its contractual duties to Brigham Young University by keeping from Brigham Young University the patentable research results and unilaterally designating a patent attorney to file and prosecute the patentable results from the Project solely for the benefit of Monsanto. Had Monsanto complied with this provision, Brigham Young University would have been alerted to Monsanto's clandestine actions.

(g) ¶ 3.6

378. Pursuant to ¶ 3.6 of the Agreement, Monsanto owed Brigham Young University a duty to bear the cost for filing and prosecution of patent applications and issuance and maintenance of patents on Brigham Young University's behalf. Monsanto also owed a duty to Brigham Young University to promptly communicate its election to not file or prosecute a patent application in adequate time to allow Brigham Young University to take such action if it so desired.

379. Monsanto breached these duties by failing to ever notify Brigham Young University of patentable results obtained from the Project.

(h) ¶ 3.7

380. Pursuant to ¶ 3.7 of the Agreement, Monsanto owed Brigham Young University a duty to, among other things, allow Brigham Young University the right to "retain patent counsel of its own who shall be permitted to review" patent applications and proposed responses to Patent Office actions and to "consult with MONSANTO'S patent attorneys."

381. Monsanto breached its contractual duties under ¶ 3.7 by interfering with Brigham Young University's ability to exercise that right. Had Monsanto complied with this provision, Brigham Young University would have been alerted to Monsanto's clandestine actions.

(i) ¶ 3.11

382. Pursuant to ¶ 3.11 of the Agreement, Monsanto owed Brigham Young University a duty to make reasonable efforts to effect the lawful introduction of licensed products into the market place as early as practicable.

383. Monsanto breached its contractual duties to Brigham Young University by failing to notify Brigham Young University that it had unilaterally patented compounds obtained through the Project and was bringing them to market unilaterally. Thus, Monsanto also breached its duty to introduce licensed products into the market on Brigham Young University's behalf and for its benefit.

(j) ¶¶ 4.1(a), (b), and (c)

384. Pursuant to ¶¶ 4.1(a), (b), and (c) of the Agreement, among other things, Monsanto owed Brigham Young University a duty to (1) hold any and all Confidential Information received pursuant to the Agreement in confidence and not to disclose such information to third parties without the written consent of the other; (2) limit the disclosure of Confidential Information to those personnel who need such access for purpose of this cooperative effort and who have undertaken the obligation to restrict the use and disclosure of

Confidential Information to the extent provided by the Agreement; and (3) to not duplicate or use Confidential Information in any other manner.

385. Among other ways, Monsanto breached the contractual duties specified above when, in 1992, Monsanto, unbeknownst to Brigham Young University, shared Confidential Information with internal Monsanto personnel conducting research including, but not limited to, secret tests on DuP-697 and its derivatives outside and separate from the Project. In further breach of the Research Agreement's confidentiality provisions, Monsanto "duplicated" Brigham Young University's Confidential Information. On information and belief, Monsanto shared confidential material with other, third-party scientists at Washington University. Further, because the confidentiality provisions of the Research Agreement extend five years from the date of disclosure of Confidential Information, even after Monsanto fraudulently terminated the Research Agreement, Monsanto's improper use of Confidential Information still breached the Agreement.

386. All Confidential Information that Dr. Simmons provided prior to the formal execution of the Agreement is covered by ¶ 4.1 for the reasons set forth above. In the alternative, either Monsanto is estopped from asserting a contrary position because Monsanto made promises to Dr. Simmons that induced his actions, or an implied-in-fact contract existed that the transmitted Confidential Information would be covered by the Agreement.

(k) ¶ 4.2

387. Pursuant to ¶ 4.2 of the Agreement, once Monsanto obtained a license from Brigham Young University, among other things, it owed Brigham Young University a duty not to furnish any third party, without Brigham Young University's prior written consent, any chemical or biological material, including DNA sequences and vectors, supplied by Brigham Young University under the Agreement.

388. Monsanto breached its contractual duties to Brigham Young University when it sent patent applications to the PTO for publication of patents and patent notices without first obtaining Brigham Young University's prior written consent.

(l) Wrongful Termination

389. Pursuant to ¶ 1.4, the Agreement was to remain in force from August 1, 1991 to July 31, 1993.

390. Monsanto breached its contractual duties to Brigham Young University by fraudulently terminating the Agreement prior to July 31, 1993 under false pretenses. Because Monsanto's termination was wrongful, it did not relieve Monsanto of its duties under the Agreement.

(m) Brigham Young University's Compliance

391. Except as excused by Monsanto's non-performance as described herein, Brigham Young University and Dr. Simmons performed all obligations on their part to be performed under the Agreement.

(n) Brigham Young University's Damages Resulting from Monsanto's Breach

392. As a direct and foreseeable result of Monsanto's breach of the Research Agreement, Brigham Young University has not received a reasonable royalty on patents that should have been filed and on patents that actually were filed (on which Dr. Simmons should be an inventor as described in Count IV below).

393. As an additional direct and foreseeable result of Monsanto's breach of Research Agreement ¶ 3.3—Monsanto's failure to notify Brigham Young University and Dr. Simmons of patentable research results obtained from the Project—Monsanto prevented Brigham Young University and Dr. Simmons from obtaining patents that would have given them the right to

block all others (including Monsanto) from selling COX-2 selective NSAIDs. Monsanto's above-described conduct was knowing, intentional, willful, deliberate, and wanton infringement of Brigham Young University and Dr. Simmons's potential patent rights justifying treble damages under 35 U.S.C. § 284.

394. Monsanto's breaches of contract have caused Brigham Young University additional damages, including pre-judgment and post-judgment interest, in amounts to be proven at trial.

395. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT II
(BREACH OF DUTY OF GOOD FAITH AND FAIR DEALING)

396. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the First Amended Complaint as though set forth in their entirety herein.

397. As a party to the Agreement, Monsanto owed Brigham Young University a duty of good faith and fair dealing.

398. Monsanto breached its duty of good faith and fair dealing when it, among other things: 1) acted to deny Brigham Young University the expected benefit of the Agreement; 2) used subterfuge and evasions to deceive Brigham Young University; 3) interpreted the Agreement in a manner inconsistent with the parties' intent and Monsanto's representations for the purpose of depriving Brigham Young University of its benefits under the Agreement; 4) induced Brigham Young University to share Confidential Information with Monsanto prior to the Agreement being signed and then treating the Confidential Information as if it was not covered by the confidentiality provisions of the Agreement; 5) induced Brigham Young University to

share its Confidential Information as part of a purported cooperative effort when Monsanto's intent was to use it solely for Monsanto's benefit; 6) used the Agreement as a tool to further Monsanto's fraudulent scheme to misappropriate the Project and related Confidential Information; and 7) otherwise failed to fulfill its obligations and duties under the Agreement.

399. Monsanto's breach of the duty of good faith and fair dealing caused Brigham Young University damages in the amount to be proven at trial.

400. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT III
(BREACH OF FIDUCIARY DUTY)

401. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

402. Monsanto assumed a fiduciary duty towards Brigham Young University and Dr. Simmons based on, among other things, the factors described in IV.G of this First Amended Complaint.

403. As a result of the fiduciary relationship, Monsanto owed Brigham Young University and Dr. Simmons a duty of loyalty, of candor, of due care and a duty to act in Brigham Young University and Dr. Simmons's best interests.

404. Monsanto breached its fiduciary duty to Brigham Young University and Dr. Simmons by wrongfully and deceitfully taking the Project and Confidential Information, using it for Monsanto's economic benefit, and generating billions of dollars in revenue from, among others, the drug Celebrex.

405. Monsanto breached its fiduciary duty to Brigham Young University by failing to advise Brigham Young University of patentable results obtained from the Project.

406. Monsanto breached its fiduciary duty to Brigham Young University and Dr. Simmons by engaging in the other deceitful and wrongful actions described in this First Amended Complaint.

407. Monsanto's actions were detrimental to Brigham Young University and Dr. Simmons, because Brigham Young University and Dr. Simmons should have benefited from the results of the Project.

408. Monsanto's breach of fiduciary duty has caused Brigham Young University and Dr. Simmons damages in an amount to be proven at trial and are a basis for the imposition of punitive damages.

409. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT IV
(CORRECTION OF INVENTORSHIP UNDER 35 U.S.C. § 256)

(United States Patent Nos. 5,344,991, 5,380,738, 5,393,790, 5,401,765, 5,418,254, 5,420,287, 5,420,343, 5,434,178, 5,466,823, 5,475,018, 5,476,944, 5,486,534, 5,504,215, 5,508,426, 5,510,496, 5,516,907, 5,521,207, 5,547,975, 5,563,165, 5,565,482, 5,576,339, 5,580,985, 5,596,008, 5,616,601, 5,620,999, 5,633,272, 5,639,777, 5,643,933, 5,663,180, 5,668,161, 5,670,510, 5,670,532, 5,672,626, 5,672,627, 5,686,470, 5,696,143, 5,700,816, 5,719,163, 5,736,579, 5,739,166, 5,753,688, 5,756,529, 5,756,530, 5,760,068, 5,859,257, 5,886,016, 5,892,053, 5,908,852, 5,910,597, 5,916,905, 5,932,598, 5,935,990, 5,972,986, 5,985,902, 5,990,148, 6,025,353, 6,028,072, 6,034,256, 6,045,773, 6,077,850, 6,090,834, 6,136,839, 6,156,781, 6,172,096, 6,271,253, 6,274,590, 6,342,510, 6,376,528, 6,407,140, 6,413,960, 6,426,360, 6,432,999, 6,436,967, 6,492,390, 6,492,411, 6,492,413, 6,496,040, 6,512,121, 6,515,014, 6,586,603, 6,599,934, 6,613,789, 6,613,790, 6,617,345, 6,649,645, 6,673,818, 6,677,634, 6,677,488, 6,696,477, 6,699,884, 6,716,829, 6,716,991, 6,753,344, 6,806,288, 6,809,111, 6,815,460, 6,822,102, 6,875,785, 6,864,373, 6,951,949, 6,964,978, 6,998,415, 7,012,094, 7,030,153, 7,109,211, 7,132,441, 7,135,489, 7,138,411, 7,141,599, 7,172,769, 7,211,597, 7,220,434, 7,220,770, 7,220,867, 7,259,222, 7,320,996, 7,420,061, 7,652,149)

410. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

411. On numerous occasions, Monsanto scientists, including, but not limited to, Bryan H. Norman, Len F. Lee, Jaime L. Masferrer, and John J. Talley, through their patent agents, filed various applications in the PTO for issuance of one or more United States patents. The PTO eventually granted many of these applications resulting in, but not limited to, the patents listed above. Dr. Simmons made essential contributions to each of these patents.

412. Based upon his activities, contributions, and inventorship prior to the filing dates of the patent applications underlying the above-listed patents, Dr. Simmons should have been listed as an inventor on each of the patents listed above. Furthermore, he would have been listed as an inventor if Brigham Young University had been accorded its rights in the patenting process as required by, among others, ¶ 3.5 of the Agreement.

413. Dr. Simmons contributed substantially to the conception of each invention forming the subject matter of the above-listed patents by providing the named inventors with data, ideas, insights, materials, and technologies that were not then publicly available and were known only to Dr. Simmons and that were the product of Dr. Simmons's own research and invention. Indeed, each of the inventions forming the subject matter of the above-listed patents would have been impossible without Dr. Simmons's unique contribution at the time of his participation in the inventive process because, among other reasons, the claimed utility of each claimed molecule and method is premised on Dr. Simmons' discovery and invention.

414. However, Dr. Simmons was wrongfully not named as an inventor on any of the patents.

415. That omission arose without any deceptive intention on the part of Brigham Young University or Dr. Simmons.

416. The above-listed patents should be corrected such that Dr. Simmons is named as an inventor thereon, and Brigham Young University should be accorded any other remedies due it under U. S. patent law.

417. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT V
(UNJUST ENRICHMENT)

418. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

419. Brigham Young University conferred a great benefit upon Monsanto by, among other things, providing Monsanto with the research, knowledge, and actual biological material from which Monsanto learned of the existence of COX-2 and the ability to develop a testing system that would lead to the discovery of COX-2 selective NSAIDs.

420. Monsanto was fully aware of the benefit conferred upon it by Brigham Young University.

421. Monsanto accepted and retained the benefit from Brigham Young University and reaped billions of dollars in revenues as a result. For the reasons described in this First Amended Complaint, Monsanto has been unjustly enriched by its acceptance of the benefit conferred upon it by Brigham Young University. Under the circumstances, it would be inequitable for Monsanto to retain those benefits.

422. Under applicable law, Brigham Young University is entitled to restitution in the amount of Monsanto's gain, including the profits from all COX-2 selective NSAIDs.

423. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT VI
(FRAUD)

424. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the First Amended Complaint as though set forth in their entirety herein.

425. Through their relationship, Monsanto made various misrepresentations to Brigham Young University. These misrepresentations include at least the following:

(a) In 1991, before Brigham Young University entered into the Agreement with Monsanto, Monsanto personnel misrepresented to Dr. Simmons that he should not get a patent on his COX-2 technology which included his isolated COX-2 and COX-2 cDNA clones, their nucleic acid sequences, and predicted amino acid sequences and his COX-2 antibodies. Upon information and belief, Monsanto was fully aware that Dr. Simmons's discoveries were patentable because of Monsanto's extensive experience in the pharmaceutical and biotechnology industry. Upon information and belief, Monsanto personnel made this misrepresentation and never corrected it because they understood that if Brigham Young University and Dr. Simmons were to patent its COX-related technology, Brigham Young University and Dr. Simmons would be in a position to control and coordinate all future research and discoveries regarding COX-2 to the exclusion of Monsanto (and all others).

(b) Prior to the execution of the July 8, 1991, Agreement, Dr. Needleman, on Monsanto's behalf, misrepresented to Dr. Simmons that Monsanto was giving Brigham Young University the same agreement Monsanto had given Dr. Needleman when he was a professor at Washington University and that the Agreement fully protected Dr. Simmons and gave Brigham Young University the right to and ownership of the results of the collaborative Project. Dr. Needleman also misrepresented to Dr. Simmons during this same time period Monsanto would enter into a full collaboration with Brigham Young University in which both Monsanto and Brigham Young University would work together in a cooperative effort to develop a COX-2 selective NSAID.

(c) On March 17, 1992, Dr. Philip Needleman sent Brigham Young University a letter on Monsanto's behalf misrepresenting that Brigham Young University had not sufficiently communicated with Monsanto.

(d) On March 23, 1992, Dr. Philip Needleman, on behalf of Monsanto, sent Dr. Simmons a letter indicating that he viewed Monsanto and Brigham Young University's relationship as "an unworkable collaboration." Dr. Needleman misrepresented five issues as the basis for his "annoyance": "(1) that you only supplied us with the first bleed of your chicken based antibody and surely you did

your own experiments with superior bleeds; (2) that you never included us in any aspect or discussion of the dexamethasone data while you knew that was a critical scientific interest of ours having discovered the phenomenon; (3) not informing us or sharing the RS-2 cells which could have been an extremely valuable screening tool for us; (4) the slowness with which you have proceeded in testing compounds; and (5) the ease with which you established outside collaborations but with no similar desire with our programs."

(e) Monsanto misrepresented in the Agreement that it would provide NSAIDs to Brigham Young University for testing.

(f) On July 27, 1992, while attending the Montreal prostaglandin conference, Dr. Needleman misrepresented to Dr. Simmons that everything relating to the Project and the termination of the Agreement had been done honestly.

(g) At the March 1997 conference in France, Dr. Needleman misrepresented to Dr. Simmons that he and his laboratory had discovered COX-2 before Dr. Simmons. Monsanto continued to misrepresent its use of Confidential Information obtained pursuant to the Agreement and the nature and extent of its own scientific discoveries as described earlier in this First Amended Complaint.

(h) In at least two patents, 5,420,343 (May 30, 1995) and 5,476,944 (December 19, 1995) Searle [Monsanto] misrepresented that it had used human or murine COX-1 or COX-2 from "Cayman Chemical, Ann Arbor, Mich." to construct its cell systems as a further fraudulent attempt to distance itself from Brigham Young University and Dr. Simmons.

(i) In various press releases and publications, Monsanto directly misrepresented, or fraudulently allowed the press to misrepresent, that Dr. Needleman, not Dr. Simmons, discovered COX-2 and conceived the concept of COX-2 selective NSAIDs as described above in Sections V.E.

(j) On March 21, 1997, in the 1996 annual report to shareholders filed with the Securities and Exchange Commission, Monsanto and Dr. Needleman misrepresented that Dr. Needleman had discovered COX-2; "Philip's research team uncovered two types of cyclooxygenase – COX-1 and COX-2."

(k) In late 1998, Monsanto misrepresented to the FDA its role in the discovery of COX-2 and the conception of COX-2 selective NSAIDs.

(l) As described in Section IX.H. above, Pfizer and its counsel have misrepresented that Dr. Simmons and Brigham Young University's Confidential Information did not work.

(m) As described in Section IX.H. above, Pfizer and its counsel have misrepresented that documents do not exist, when in fact the documents do exist and have made other discovery related misrepresentations.

(n) As described in Exhibits B and C, Pfizer and its counsel misrepresented the status of its search for and production of biological materials and documents from prior litigation.

426. The misrepresentations in ¶ 425 (h)-(k) were not made directly to Brigham Young University or Dr. Simmons but illustrate a portion of Monsanto's campaign to misrepresent facts to its investors, elected officials, governmental regulatory agencies, the public and to the scientific community of which Dr. Simmons was a part.

427. In addition to the direct misrepresentations Monsanto made to Brigham Young University, Dr. Simmons, and the public, Monsanto made misrepresentations to Brigham Young University by way of fraudulent omissions.

428. As a party to a business transaction with and related duties running to Brigham Young University, Monsanto was obligated to disclose:

(a) Matters known to Monsanto by virtue of the fiduciary duty described above;

(b) Matters that Monsanto knew Brigham Young University would need to understand in order to make Monsanto's other statements not misleading;

(c) Subsequently acquired information that Monsanto knew would make previous statements untrue or misleading;

(d) Untrue statements Monsanto originally thought Brigham Young University would not rely on, when Monsanto realized that Brigham Young University was in fact relying on them;

(e) Facts basic to the Agreement that Monsanto knew Brigham Young University was mistaken about and that Monsanto knew Brigham Young University expected it to disclose based on their relationship; and

(f) All material information that the Agreement, including ¶ 1.6 and ¶ 3.3, obligated Monsanto to disclose to Brigham Young University.

429. Therefore, Monsanto was under a duty to disclose to Brigham Young University and Dr. Simmons at least the following:

(a) Monsanto secretly began a parallel Project seeking a COX-2 inhibiting NSAID with the use of the Confidential Information.

(b) Monsanto tested DuP-697 and found it to be COX-2 selective and a potential lead compound in the search for a COX-2 selective inhibitor.

(c) Brigham Young University could have applied for various patents, including those described in ¶ 95 of this First Amended Complaint. Contrary to its obligation to do so, Monsanto failed to correct its prior misrepresentations.

(d) Monsanto and Dr. Needleman did not intend to enter into a collaborative Project with Brigham Young University that would provide Brigham Young University with the rights to and ownership of the results of the Project, but intended to use the Agreement as a method of taking the Project and Confidential Information for its own use and economic benefit.

(e) Monsanto terminated the Agreement with Brigham Young University not because Dr. Simmons was uncommunicative or for the other stated reasons, but because Monsanto intended to use Confidential Information to create COX-2 selective NSAIDS while excluding Brigham Young University from the economic benefits to which it was entitled under the Agreement.

430. All of the misrepresentations and omissions listed above were material to the status of the research Project between Monsanto and Brigham Young University.

431. The respective Monsanto representatives knew the statements were false when they made them. In the case of omissions, Monsanto knew it had omitted disclosing material information to Brigham Young University and Dr. Simmons. Monsanto intended and reasonably contemplated that Brigham Young University and Dr. Simmons would rely, either directly or indirectly, on the misrepresentations and omissions by not pursuing their economic rights resulting from the Project.

432. Brigham Young University was unaware that Monsanto's misrepresentations were false until years later when Dr. Simmons discovered, through Monsanto's litigation, that Monsanto had not independently identified or isolated COX-2 and did not have its own project to search for a COX-2 selective NSAID prior to Dr. Simmons bringing it to them. Rather, Monsanto made misrepresentations designed to deceive Brigham Young University and Dr. Simmons, terminate the relationship with Brigham Young University, deny Brigham Young University and

Dr. Simmons of their rightful professional and economic expectancies, and thwart their reasonable and diligent actions to uncover the truth.

433. Brigham Young University and Dr. Simmons reasonably and justifiably relied upon the truth of Monsanto's misrepresentations, had a right to rely thereupon, and were unaware of the truth because of Monsanto's concealment and misleading conduct.

434. As a consequence of Brigham Young University and Dr. Simmons's justifiable reliance upon Monsanto's misrepresentation, Brigham Young University and Dr. Simmons have been caused damage in an amount to be proven at trial.

435. Because Monsanto's fraudulent conduct is willful and malicious, intentionally fraudulent, or manifests a knowing and reckless indifference toward, and a disregard of, the rights of others, Brigham Young University and Dr. Simmons should be awarded punitive damages in an amount to be proven at trial.

436. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT VII
(NEGLIGENT MISREPRESENTATION)

437. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the First Amended Complaint as though set forth in their entirety herein.

438. Throughout their relationship, Monsanto made various misrepresentations and omissions to Brigham Young University and Dr. Simmons as more extensively enumerated in COUNT VI (Fraud), above.

439. In the alternative to the above alleged fraud claim, Brigham Young University and Dr. Simmons allege that Monsanto made the misrepresentations and omissions negligently.

440. Monsanto had a pecuniary interest in its relationship with Brigham Young University and Dr. Simmons relating to Dr. Simmons's isolation and identification of COX-2 and the related technology. Monsanto supplied Brigham Young University and Dr. Simmons false information for guidance in their business transaction.

441. Monsanto was in a superior position over Brigham Young University to know the material facts regarding, among other things, whether Dr. Simmons's technology was patentable, whether other results obtained from the Project were patentable, how Monsanto used Dr. Simmons's Confidential Information, and whether Dr. Needleman had in fact discovered COX-2.

442. Monsanto carelessly or negligently made false representations and omissions.

443. Monsanto expected Brigham Young University and Dr. Simmons to rely and act upon Monsanto's representations and omissions.

444. Brigham Young University and Dr. Simmons did reasonably rely on Monsanto's representations and omissions, and Brigham Young University and Dr. Simmons suffered damages in an amount to be proven at trial.

445. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT VIII
(VIOLATION OF THE UNIFORM TRADE SECRET ACT,
UTAH CODE ANN. § 13-24-2, ET SEQ.)

446. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the First Amended Complaint as though set forth in their entirety herein.

447. At the time Dr. Simmons made his April 5, 1991, presentation at Monsanto, and during the course of all subsequent dealings with Monsanto, Dr. Simmons and Brigham Young

University maintained "trade secrets" related to their COX-2 discovery and research. These "trade secrets" included, but were not limited to, Dr. Simmons and Brigham Young University's COX-2 mRNA, nucleic acid sequences, mRNA samples containing COX-2 mRNA, complete COX-1 and COX-2 clones, assays for determining COX-2 selectivity and all other technical direction, and advice and information provided by Dr. Simmons and others who worked with him at Brigham Young University over the telephone and in person during the course of their cooperative effort.

448. Each "trade secret" held by Dr. Simmons and Brigham Young University derived independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who could obtain economic value from its disclosure or use. Specifically, Dr. Simmons and Brigham Young University's COX-2 mRNA sequence, COX-1 and COX-2 clones and antibodies, and assays for determining COX-2 selectivity could be used to develop a COX-2 selective NSAID. But this discovery's value would be minimized if these "trade secrets" were disclosed.

449. Therefore, Dr. Simmons and Brigham Young University took reasonable efforts to maintain the secrecy of the "trade secrets." These efforts included refraining from publishing the murine COX-2 nucleic acid sequence and refusing to deliver his murine COX-1 and COX-2 clones and antibodies to Monsanto until Brigham Young University and Monsanto orally agreed that the Confidential Information would receive the protection of the confidentiality provisions contained in the draft agreement provided to Brigham Young University. In fact, Dr. Needleman repeatedly represented that Brigham Young University would receive the same protection he had received at Washington University in connection with dealing with Monsanto.

450. Monsanto willfully and maliciously and in bad faith misappropriated Dr. Simmons and Brigham Young University's "trade secrets" by disclosing and using them without express or implied consent despite the fact that Monsanto acquired the "trade secrets" under circumstances giving rise to a duty to maintain their secrecy and limit their use. Specifically, by July 8, 1991, the Agreement obligated Monsanto to protect Dr. Simmons and Brigham Young University's Confidential Information that was comprised of its "trade secrets." Additionally, both before the Agreement was put in force and after it was terminated, Dr. Simmons and Brigham Young University's express statements or implied terms made clear that Monsanto was not to use these "trade secrets" outside of the collaborative effort. Alternatively, on information and belief, Monsanto used improper means, including fraudulent inducements, to acquire knowledge of the "trade secrets."

451. Dr. Simmons and Brigham Young University acted reasonably and diligently and could not have discovered Monsanto's misappropriation through the exercise of due diligence before Dr. Simmons's reading of the Peter Isakson statement.

452. Dr. Simmons and Brigham Young University should be awarded attorney fees, injunctive relief, damages comprising actual loss, unjust enrichment, or a reasonable royalty for Monsanto's unauthorized use of the "trade secrets." Additionally, due to the malicious and willful character of Monsanto's misappropriation, Dr. Simmons and Brigham Young University should be awarded punitive/exemplary damages pursuant to Utah Code Ann. § 13-24-4.

453. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT IX
(VIOLATION OF 18 U.S.C. § 1962(c))

454. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the First Amended Complaint as though set forth in their entirety herein.

455. The Defendants, and each of them, are "persons" within the meaning of 18 U.S.C. §§ 1961(3) and 1962(c).

456. The COX-2 Project Enterprise, as described in Section IX.A. above, constitutes an "enterprise" as defined in 18 U.S.C. §§ 1961(4) and 1962(c).

457. The COX-2 Project Enterprise was engaged in interstate commerce at all times relevant to this First Amended Complaint.

458. Each of the individual Defendants were and are associated with the COX-2 Project Enterprise and have conducted or participated, directly or indirectly, in the management and operation of the affairs of the Enterprise through a pattern of activity unlawful under 18 U.S.C. §§ 1961(B) including mail fraud (18 U.S.C. § 1341), wire fraud (18 U.S.C. § 1343), and obstruction of justice (18 U.S.C. § 1503).

459. The Defendants acts of mail fraud, through the COX-2 Project Enterprise, include the following, each sent through the U.S. Mail and each part of an artifice or scheme to defraud:

INTERSTATE TRAVEL

Date	From	To	Who	Description	Relation to the Scheme
4/5/91	Provo, UT	St. Louis, MO	Dr. Simmons	At Monsanto's request, Dr. Simmons travelled to Monsanto's headquarters to present a seminar on his discovery.	Misappropriation of Confidential Information and of the Project

Date	From	To	Who	Description	Relation to the Scheme
7/1991	Provo, UT	St. Louis, MO	Dr. Bradshaw	When Monsanto requested additional materials, Dr. Bradshaw went to Monsanto to report on all activities at BYU and to deliver the materials.	Misappropriation of Confidential Information and of the Project
12/1/98	St. Louis, MO	Silver Spring, MD	Dr. Needleman Dr. Isakson	Individuals from Monsanto, including Dr. Needleman and Dr. Isakson, traveled to the FDA offices and made the following statements: (a) "[W]e watched from the birth of the concept of the COX-2 inhibitors in our laboratories to the fruition and completion of a major clinical trial." (b) "A second enzyme, a uniquely induced enzyme as we thought in 1990, we named COX-2…" (c) "Based on the existence of COX-2, we then developed specific COX-2 inhibitors that could go after these rational drug targets but be devoid and spare COX-1 activity."	Fraudulent Concealment
7/11/01	St. Louis, MO	Washington, DC	Dr. Needleman	Dr. Needleman testified before the Labor, Health and Human Services, and Education Subcommittee of the US Senate that "Our studies into the underlying processes that cause the swelling, pain and stiffness of osteo-and rheumatoid-arthritis led to the discovery of a protein-gene called Cox-2 (cyclooxygenase) that is not present in normal stomach or colon tissue but is turned on by tissue injury, inflammation, and various body chemicals released by disease processes."	Fraudulent Concealment

MAIL/WIRE FRAUD

Date	From	To	Description	Relation to the Scheme
4/9/91	Dr. Needleman St. Louis, MO	Dr. Simmons Provo, UT	Dr. Needleman represented that "[y]ou will be receiving an agreement from our patent attorney which follows the spirit of our successful agreement with Washington University."	Misappropriation of Confidential Information and of the Project
4/11/91	LR Swaney St. Louis, MO	Dr. Simmons Provo, UT	Monsanto patent attorney Swaney sent a draft Research Agreement to BYU.	Misappropriation of Confidential Information and of the Project
4/29/91	Dr. Simmons Provo, UT	Dr. Seibert Dr. Masferrer St. Louis, MO	Dr. Simmons provided Seibert and Masferrer with his biological materials.	Misappropriation of Confidential Information and of the Project
5/16/91	Dr. Needleman St. Louis, MO	Dr. Simmons Provo, UT	Dr. Needleman represented that, in collaborating with BYU, "[w]e will follow the basic guidelines of the Washington University/Monsanto agreement."	Misappropriation of Confidential Information and of the Project
5/23/91	Dr. Simmons Provo, UT	Dr. Needleman St. Louis, MO	Dr. Simmons provided Monsanto with a copy of his NIH grant proposal.	Misappropriation of Confidential Information and of the Project
7/8/91	Monsanto St. Louis, Mo.	BYU Provo, UT	Monsanto and BYU signed the Research Agreement and exchanged it via US mail between Missouri and Utah.	Misappropriation of Confidential Information and of the Project
7/16/91	BYU	Monsanto	BYU faxed amino acid comparisons for COX 1 and COX 2 to Monsanto.	Misappropriation of Confidential Information and of the Project
91-92	Dr. Simmons Provo, UT	Dr. Seibert Dr. Masferrer St. Louis, MO	Monsanto and Dr. Simmons exchanged more than 60 telephone calls to discuss the collaboration.	Misappropriation of Confidential Information and of the Project

Date	From	To	Description	Relation to the Scheme
3/17/92	Dr. Needleman St. Louis, MO	Dr. Simmons Provo, UT	Dr. Needleman raised a list of alleged problems with the collaboration and stated "[w]e should give serious consideration to ending the grant at the end of one year."	Fraudulent termination of the contract and continued misappropriation of Confidential Information and of the Project
3/20/92	Dr. Simmons Provo, UT	Dr. Needleman St. Louis, MO	Dr. Simmons addressed the issues raised by Dr. Needleman and expressed his desire to remain in an open collaboration.	Fraudulent termination of the contract and continued misappropriation of Confidential Information and of the Project
3/23/92	Dr. Needleman St. Louis, MO	Dr. Simmons Provo, UT	Needleman claimed the collaboration was "unworkable."	Fraudulent termination of the contract and continued misappropriation of Confidential Information and of the Project
3/27/92	BYU Provo, UT	Monsanto St. Louis, MO	BYU sent a letter acknowledging termination of the Research Agreement.	Fraudulent termination of the contract and continued misappropriation of Confidential Information and of the Project
05/92	PNAS	Widespread distribution	*Endogenous glucocorticoids regulate an inducible cyclooxygenase enzyme*	Fraudulent Concealment
1/15/93	Monsanto St. Louis, MO	U.S. PTO Washington, DC	Monsanto applied for a patent on 3,4 diaryl thiophenes, naming Steve Bertenshaw as the sole inventor.	Fraudulent Concealment
4/94	PNAS	Widespread distribution	*Selective inhibition of inducible cyclooxygenase 2 in vivo is anti-inflammatory and nonulcerogenic*	Fraudulent Concealment
5/19/94	Monsanto St. Louis, MO	U.S. PTO Washington, DC	In the application for US Patent No. 5,476,944, Monsanto misrepresented that its cell testing systems were constructed using human or murine COX-1 or COX-2 fragments from "Cayman Chemical, Ann Arbor, Mich."	Fraudulent Concealment

Date	From	To	Description	Relation to the Scheme
8/31/94	Monsanto St. Louis, MO	US PTO Washington, DC	In the application for US Patent No. 5,420,343, Monsanto misrepresented that its cell testing systems were constructed using human or murine COX-1 or COX-2 fragments from "Cayman Chemical, Ann Arbor, Mich."	Fraudulent Concealment
12/94	PNAS	Widespread distribution	*Pharmacological and biochemical demonstration of the role of cyclooxygenase 2 in inflammation and pain*	Fraudulent Concealment
7/8/96	M2 Press Wire	Widespread distribution	Monsanto caused M2 Press Wire to issue a press release which attributed the discovery of COX-2 to Needleman and did not mention Dr. Simmons.	Fraudulent Concealment
11/4/96	Biotech. News Watch	Widespread distribution	Press release which attributed the discovery of COX-2 to Dr. Needleman and omitted mention of Dr. Simmons.	Fraudulent Concealment
3/21/97	Monsanto St. Louis, MO	SEC/ shareholders worldwide	In a 1996 annual report, which was filed with the SEC, Monsanto attributed the discovery of COX-2 to Dr. Needleman.	Fraudulent Concealment
12/14/98	U.S. News and World Report	Widespread distribution	Press release which attributed the discovery of COX-2 to Dr. Needleman and omitted mention of Dr. Simmons.	Fraudulent Concealment
Late 1998	BYU Provo, UT	Monsanto St. Louis, MO	During a telephone call, Monsanto denied having ever worked with Dr. Simmons or knowing who he was.	Fraudulent Concealment
1/99	Joe Bulock St. Louis, MO	Eugene Bramhall Provo, UT	In a telephone call, Bulock denied the allegations in Bramhall's 12/9/1999 letter.	Fraudulent Concealment
11/10/99	PR Newswire	Widespread distribution	Press release which attributed the discovery of COX-2 to Dr. Needleman and omitted mention of Dr. Simmons.	Fraudulent Concealment
3/10/00	PR Newswire	Widespread distribution	Press release which discussed the discovery of COX-2 and omitted mention of Dr. Simmons.	Fraudulent Concealment

Date	From	To	Description	Relation to the Scheme
3/17/00	Dale Hoscheit Washington, DC	Eugene Bramhall Provo, UT	Hoscheit wrote a letter denying BYU's allegations, claiming: (a) Monsanto scientists "… were not successful in obtaining meaningful replication [of Simmons's mouse COX-2]." (b) Monsanto had obtained another mouse COX-2 cDNA construct from a third-party source. (c) Monsanto did not obtain "an immediate, significant and unique advance" in this area because of Professor Simmons. (d) It was not until Monsanto modified another mouse COX-2 construct from a third party source in 1992 that it was able to gain meaningful expression and Monsanto's testing with mouse COX-2 was based upon that later effort.	Fraudulent Concealment
5/17/00	Dale Hoscheit Washington, DC	Eugene Bramhall Provo, UT	Monsanto represented, among other things, that "[b]y the end of 1991, Dr. Seibert essentially ceased to work with the Simmons' COX-2 clone."	Fraudulent Concealment
2/22/02	PR Newswire	Widespread distribution	Two press releases which discussed the discovery of COX-2 and omitted mention of Dr. Simmons.	Fraudulent Concealment

460. The Defendants, acting through the COX-2 Project Enterprise, have committed repeated violations of 18 U.S.C. § 1503.

a. *Brigham Young University v. Pfizer*, case number 2:06CV-890, is a judicial proceeding currently pending in this Court.

b. Because they are parties to *Brigham Young University v. Pfizer*, the Defendants have knowledge of the proceeding.

c. Based on the detailed evidence described in Section IX.H, above, the Defendants possess a corrupt intent to obstruct justice by unlawfully withholding documents.

d. The Defendants' conduct, described in Section IX.H, above, was performed with that corrupt intent.

e. Because the Defendants' conduct has obstructed the due administration of justice in this case causing, delay, significant legal fees and costs, and preventing the Plaintiffs from obtaining relevant evidence, there is a nexus between the Defendants' conduct and this case.

461. As a direct and proximate result of the violation of 18 U.S.C. § 1962(c) committed by the Defendants, Brigham Young University and Dr. Simmons have suffered substantial injury to their business or property within the meaning of 18 U.S.C. § 1964(c).

462. Among other injuries to Brigham Young University's business or property, the Defendants injured Brigham Young University's valuable interest in the Project in an amount to be proven at trial.

463. For the Defendants' violation of 18 U.S.C. § 1962(c), Brigham Young University and Dr. Simmons should be awarded damages pursuant to 18 U.S.C. § 1964(c), including but not limited to three times their actual damages, their costs, and their fees.

464. Also for their violation of 18 U.S.C. § 1962(c), the Defendants should be ordered to disgorge the economic benefits they obtained through the operation of the COX-2 Project Enterprise.

465. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

COUNT X
(VIOLATION OF 18 U.S.C. § 1962(d)
BY CONSPIRING TO VIOLATE § 1962(c))

466. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the First Amended Complaint as though set forth in their entirety herein.

467. The Defendants, and each of them, are "persons" within the meaning of 18 U.S.C. §§ 1961(3), 1962(c) and 1962(d).

468. The COX-2 Project Enterprise constitutes an "enterprise" as defined in 18 U.S.C. §§ 1961(4) and 1962(c).

469. Each of the Defendants were and are associated with the COX-2 Project Enterprises and conspired within the meaning of 18 U.S.C. § 1962(d) to violate 18 U.S.C. § 1962(c), that is, the Defendants conspired to conduct or participate, directly or indirectly, in the management and operation of the affairs of the COX-2 Enterprise in relationship to the Plaintiffs through a pattern of activity unlawful under 18 U.S.C. § 1961(B) including mail fraud (18 U.S.C. § 1341), wire fraud (18 U.S.C. § 1343), and obstruction of justice (18 U.S.C. § 1503), which is described in Count IX above.

470. The Defendants joined the conspiracy to violate 18 U.S.C. § 1961(c) as follows:

a. Monsanto and its pharmaceutical subsidiary Searle were the original members of the conspiracy, which began at some time prior to March 17, 1992, when

Monsanto decided to fraudulently terminate the Research Agreement and misappropriate the Project;

b. Pfizer joined the conspiracy sometime before 1998, when it partnered with Monsanto to market Celebrex; and

c. Pharmacia joined the conspiracy when it merged with Monsanto in April 2000.

471. The Defendants conspiracy to violate 18 U.S.C. § 1962(c) is ongoing.

472. As a direct and proximate result of the violation of 18 U.S.C. § 1962(d) committed by the Defendants, Brigham Young University and Dr. Simmons have suffered substantial injury to their business or property within the meaning of 18 U.S.C. § 1964(c).

473. Among other injuries to its business or property, the Defendants' conspiracy to violate 18 U.S.C. § 1962(c) injured Brigham Young University's valuable interest in the Project in an amount to be proven at trial.

474. For the Defendants' violation of 18 U.S.C. § 1962(d), Brigham Young University and Dr. Simmons should be awarded damages pursuant to 18 U.S.C. § 1964(c), including but not limited to three times their actual damages, their costs, and their fees.

475. Also for their violation of 18 U.S.C. § 1962(d), the Defendants should be ordered to disgorge the economic benefits they obtained through the operation of the COX-2 Project Enterprise.

476. Brigham Young University and Dr. Simmons seek the additional relief set forth below in their Prayer for Relief.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants as follows:

A. All items of damages requested in the above-listed counts;

B. For actual damages in an amount to be proven at trial or motion, including damages to Brigham Young University and Dr. Simmons;

C. For a directive to issue to the Commissioner of the United States Patent and Trademark Office instructing said Commissioner to issue a certificate of correction in connection with the patents listed in Count IV above attesting to the fact that Dr. Simmons was erroneously omitted as an inventor on those patents and correcting that error by including Professor Simmons among the listed inventors.

D. For disgorgement of the economic benefits obtained by the Defendants through the operation of the COX-2 Project Enterprise;

E. For prejudgment and post-judgment interest as allowed pursuant to statutory and common law;

F. For punitive damages in an amount to be determined at trial;

G. For attorneys' fees, costs, and expenses of litigation as may be allowed pursuant to statutory and common law;

H. For all other damages provided for by statute; and

I. For such other relief as the Court deems just and proper.

DATED this 1st day of July 2010.

BEUS GILBERT PLLC

By s/Leo R. Beus
Leo R. Beus
L. Richard Williams
Mark C. Dangerfield
Adam C. Anderson
Keith C. Ricker

RAY QUINNEY & NEBEKER P.C.
Mark M. Bettilyon
Rick B. Hoggard
Arthur B. Berger
Samuel C. Straight

OFFICE OF THE GENERAL COUNSEL
David B. Thomas
BRIGHAM YOUNG UNIVERSITY

CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of July 2010, I electronically filed the foregoing FIRST AMENDED COMPLAINT with the Clerk of the United States District, District of Utah Central Division, using the CM/ECF system which sent notification of such filing to the following:

Charles W. Douglas, Esq. Richard O'Malley, Esq. Lisa A. Schneider, Esq. Neil H. Wyland, Esq. Sidley Austin LLP One South Dearborn Chicago, IL 60603 Telephone: 312-853-3577 Facsimile: 312-853-7036 cdouglas@sidley.com romalley@sidley.com lschneider@sidley.com nwyland@sidley.com	George Haley, Esq. David R. Parkinson, Esq. Holme Roberts & Owen LLP 299 South Main Street Suite 1800 Salt Lake City, UT 84111 Telephone: 801-521-5800 Facsimile: 801-521-9639 george.haley@hro.com david.parkinson@bro.com
Dan K. Webb Raymond C. Perkins WINSTON & STRAWN LLP 35 W. Wacker Drive Chicago, IL 60601 Telephone: 312-558-5600 Facsimile: 312-558-5700 dwebb@winston.com dperkins@winston.com	John Caleb Dougherty Richard T. Mulloy Kathy J. Owen DLA PIPER 6225 Smith Avenue Baltimore, MD 21209 Telephone: 410-580-4140 Facsimile: 410-580-3140 john.dougherty@dlapiper.com richard.mulloy@dlapiper.com kathy.owen@dlapiper.com

s/Adam C. Anderson